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Agency

Office of Ground Water
and Drinking Water
Cincinnati, OH 45268

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MANUAL FOR THE CERTIFICATION OF LABORATORIES ANALYZING DRINKING WATER

Criteria and Procedures Quality Assurance

Fourth Edition

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Supersedes EPA/570/9-90/008, April 1990,
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US Environmental Protection Agency
Office of Water
Office of Ground Water and Drinking Water
Technical Support Center
Cincinnati, Ohio 45268

Disclaimer

This manual has been reviewed and approved for publication by the Office of Ground Water and Drinking Water, the Office of Research and Development and the 10 EPA Regional Offices. The mention of commercial products does not constitute endorsement by the U.S. Environmental Protection Agency.

This manual applies specifically to activities conducted by the U.S. EPA. States that adopt this manual must make appropriate changes so the language applies accurately to their State certification programs.

Regulatory changes made subsequently to the publication of this manual take precedence over this manual.

Acknowledgments

This edition of the manual was prepared through the efforts of many individuals, including representatives from the U.S. Environmental Protection Agency Office of Ground Water and Drinking Water (OGWDW), Office of Research and Development (ORD) and Regional Offices and the States. It has as its foundation, previous editions of the manual. Contributors to the previous editions of the manual are listed in EPA documents EPA/570/9-90/008, April 1990, EPA-570/9-82-002 October 1982 and EPA 600/8-78-008 May 1978. Contributors to this edition are listed below.

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Preface

Since 1978, the U. S. Environmental Protection Agency (EPA) has implemented a certification program for laboratories performing drinking water analyses for compliance with regulations issued pursuant to the Safe Drinking Water Act. These laboratories include EPA Regional laboratories, certain Federal laboratories, laboratories on Indian lands, principal State laboratories in primacy States, and drinking water laboratories in non-primacy States. The elements described in this manual are required for EPA programs. **Only those elements which are in the drinking water regulations are mandatory for the States.** However, in order to provide consistency in how the program is implemented across the country, the States are encouraged to comply with all requirements in this manual.

This document is the fourth edition of the manual, describing the program's implementation procedures and technical criteria. It supersedes the Manual for the Certification of Laboratories Analyzing Drinking Water, EPA-570/9-90-008 (April 1990) and Changes 1 (October 1991) and 2 (September 1992). The effective date of this manual is six months from the date of publication.

This revision was necessary to: 1) address the reorganization in the EPA Offices; 2) provide more consistency in the way the program is implemented; 3) address the increased complexity of the revised drinking water regulations; 4) clarify Regional responsibilities concerning State laboratory certification programs; 5) describe the length of time a laboratory can be "provisionally certified"; 6) define "interim" certification; and 7) improve feedback to EPA on how laboratories perform on a routine basis. This edition resulted from an ongoing review of the laboratory certification program. Its goal is to improve implementation of the SDWA in light of newly approved methodology and additional experience with the program.

This document was prepared by a committee chaired by the EPA's Office of Ground Water and Drinking Water (OGWDW) with participation of the National Exposure Research Laboratories in Cincinnati (NERL-Ci) and Las Vegas (NERL-LV) and representatives from the ten U.S. EPA Regions and from the States.

Like previous editions, this edition is in loose-leaf format which will allow the EPA to update it more easily. Holders of this manual should check with the EPA Region or the State Certification Officers to make sure their manual is current. Additional copies of this manual may be obtained from the U.S. EPA, OGWDW, 26 W M.L. King Dr., Cincinnati, OH, 45268, fax number 513.569.7191. Copies may also be obtained by calling the Safe Drinking Water Hotline at 800.426.4791. The manual is posted on the Internet at www.epa.gov/OGWDW/pubs.html.

To ensure uniformity in the application of the certification program in all the Regions, internal policy requires EPA to use the certification criteria in this manual for evaluating all public, commercial and State drinking water laboratories that it certifies. For the purposes of this document, public laboratories include county, municipal, utility, and Federal. The Agency must also use this manual to determine the adequacy of State certification programs for drinking water laboratories. States are encouraged to use the criteria in this manual to evaluate all laboratories that they certify.

This manual uses the terms "shall" and "must" interchangeably to refer to elements that are required by the National Primary Drinking Water Regulations or the approved drinking water methods. These terms are also used for items required by EPA policy or which have universal agreement. The term "should" refers to items that EPA **highly recommends.**

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Chapter I
Introduction

Public water systems serving at least 25 persons or having at least 15 service connections must comply with the Safe Drinking Water Act (SDWA) and the requirements of the National Primary Drinking Water Regulations (NPDWR) (40 CFR 141). Section 1401(1)(D) of the Act defines a National Primary Drinking Water Regulation to include "criteria and procedures . . . [for] quality control and testing procedures to insure compliance . . . " 40 CFR 142 sets implementation requirements.

The regulations governing primacy at 40 CFR 142.10(b)(4) require a State that has primary enforcement responsibility (primacy) to have laboratory facilities available (the Principal State Laboratory) which have been certified by EPA. In addition, the regulations governing certification (40 CFR 141.28) require that all testing for compliance purposes be performed by laboratories certified by the State or by EPA except that turbidity, free chlorine residual, temperature, and pH may be performed by anyone acceptable to the State. This manual is intended to assist EPA in implementing 40 CFR 142.10(b)(4) by specifying criteria and procedures for certifying principal State laboratories. States with primacy may also choose to use equivalent criteria and procedures similar to those in this manual for their own certification programs.

To obtain and maintain primacy, a State must comply with 40 CFR 142.10, which includes the following provisions:

> The establishment and maintenance of a State program for the certification of laboratories conducting analytical measurements of drinking water contaminants pursuant to the requirements of the State primary drinking water regulations including the designation by the State of a laboratory officer, or officers, certified by the Administrator, as the official(s) responsible for the State's certification program. The requirements of this paragraph may be waived by the Administrator for any State where all analytical measurements required by the State's primary drinking water regulations are conducted at laboratories operated by the State and certified by the Agency. (40 CFR 142.10(b)(3)(i))
>
> Assurance of the availability to the State of laboratory facilities certified by the Administrator and capable of performing analytical measurements of all contaminants specified in the State primary drinking water regulations . . . (40 CFR 142.10(b)(4)).

Reference to the Administrator of EPA also refers to his or her designee.

The EPA laboratory certification program extends to its Regional laboratories, laboratories on Federal Indian Lands, principal State laboratories in primacy States, and laboratories that perform analyses under the Safe Drinking Water Act in States without primacy. If all analyses are not performed in principal State laboratories, primacy States must have a certification program for certifying other drinking water laboratories.

EPA's National Exposure Research Laboratory in Cincinnati, Ohio (NERL-Ci), is responsible for determining the certification status for EPA Regional laboratories in microbiology and chemistry. The National Exposure Research Laboratory in Las Vegas (NERL-LV) has this responsibility for radiochemistry. Regional certification officers are responsible for the certification of the principal State laboratory in each primacy State and are also responsible for certifying all laboratories on Federal Indian Lands and in non-primacy States. Primacy States with certification programs are responsible for certifying the other drinking water laboratories in their State, (i.e., laboratories other than the principal State Laboratory).

Regional laboratories must successfully analyze a set of performance evaluation samples (PEs) at least annually for all regulated contaminants for which they wish to be certified and pass an on-site evaluation at least every three years.

At least annually, Principal State laboratories must successfully analyze a complete set of unknown performance evaluation (PE) samples from a source acceptable to the Region for the contaminants included in the regulations which the State has adopted, and pass an on-site evaluation every three years. For radiochemistry certification, satisfactory performance on additional PEs may also be required. EPA policy requires the use of the criteria in this manual for the on-site audits of the Regional and principal State laboratories.

Chapter II describes the responsibilities of each of the parties involved in the certification program. Chapter III describes how the program operates. Chapters IV, V and VI cover the technical criteria to be used during the on-site evaluation of a laboratory for chemistry, microbiology, and radiochemistry, respectively. Optional audit forms are also included in Chapters IV, V and VI. The appendices include the following: a recommended protocol and format for conducting on-site laboratory evaluations, which may be used by the laboratory auditors; frequently used abbreviations and definitions; EPA's policy on third-party auditors; a list of contaminants a principal State laboratory must have the capability to analyze; a list of contaminants in proposed rules; a list of unregulated chemicals for which systems must monitor under §1445 of the Safe Drinking Water Act; optional record keeping and data audit procedures; and recommended chain-of-custody procedures to be used if necessary.

Chapter II
Responsibilities

The success of the laboratory certification program depends upon cooperation among the organizations responsible for its implementation. Within the Agency, responsibilities for laboratory certification are shared by the Office of Ground Water and Drinking Water (OGWDW), the Office of Research and Development (ORD), and the Regional Offices.

Office of Ground Water and Drinking Water (OGWDW) and Office of Research and Development (ORD)

OGWDW and ORD share the responsibility for developing and implementing the national certification program for laboratories that analyze drinking water samples and for implementing the Safe Drinking Water Act. These responsibilities include the following:

- Propose and promulgate regulations;
- Assess national laboratory capacity and capability;
- Review the EPA Regional certification programs annually and evaluate the resources and personnel available in each EPA Region to carry out the certification program;
- Develop guidance and respond to questions and comments;
- Develop technical and administrative certification criteria to support future regulations;
- Assess the capacity and capability of the EPA Regional laboratories;
- Revise this manual when necessary;
- Conduct triennial on-site audits of each Regional laboratory for chemistry and microbiology and principal State laboratories for radiochemistry (if requested by the Region);
- Prepare and distribute performance evaluation (PE) samples (Water Supply Studies) for regulated chemical, microbiological and radiological contaminants semiannually and evaluate and distribute the results of these studies;
- Develop and participate in training courses to support the certification program;
- Provide technical assistance to EPA and the States;
- Develop and evaluate methods for the analysis of drinking water contaminants.

NERL-LV is the lead organization for managing the certification program for laboratories performing radiochemical analyses. At the request of a Region, NERL-LV is responsible for conducting triennial on-site audits of principal State laboratory systems for radiochemistry. In these cases, NERL-LV must report the results of its on-site audits to the responsible Regional certification authority, who has the final authority to determine certification status.

EPA Regions

The Regions oversee the certification programs in the States. The Regions' responsibilities are:

- Determine the certification status for the principal State laboratory system in each primacy State;
- Coordinate NERL water supply performance evaluation studies with laboratories in the Region (some Regions have delegated this responsibility to the States);
- Perform an annual review of State certification programs and performance evaluation results and monitor the adequacy of State programs for certifying laboratories, as described in Chapter III;
- Provide technical assistance to the States' EPA-certified drinking water laboratories, as needed;
- Manage the certification program for drinking water laboratories in non-primacy States and on Federal Indian lands using the criteria in this manual.

This last duty may be performed by the State, but the Region must retain responsibility for the on-site evaluation of the designated principal State laboratory. Drinking water laboratories may be evaluated by the Region, or under a Region-approved program carried out by a designated State program. In either case, this manual must be the basis for

the on-site audits, conducted by EPA, of principal State laboratories, laboratories on Federal Indian lands, and drinking water laboratories in non-primacy States.

The Regional laboratory should maintain certification for as many regulated contaminants as its resources permit. It enhances both EPA's technical assistance capabilities and credibility with those it certifies. It also ensures the laboratory capability to analyze samples for possible enforcement actions and for States which do not have primacy. Reciprocal agreements with other regions to share scarce resources may be needed.

Primacy States

Primacy States are required to establish and maintain a State program for the certification of laboratories conducting analyses of drinking water compliance samples, unless all compliance samples are analyzed in the State laboratory.

The States must designate a certification officer or officers, certified by the EPA administrator or his or her designee as the person responsible for the certification program.

States are responsible for the certification of the public and private laboratories in their State. This includes auditing the laboratories and reviewing the PE data. States should also provide technical assistance to laboratories. They may also choose to certify laboratories outside their State either by an on-site evaluation or reciprocity.

Chapter III
Implementation

Evaluation of Certification Programs

The Regions and OGWDW should monitor the certification programs under their purview annually. The adequacy of programs for certifying laboratories is evaluated by assessing each program's scope, staffing, resources, policy, procedures, and effectiveness. This should be done in person during an on-site audit when possible and at least by means of a questionnaire in the other years. The adequacy of these essential program elements is evaluated by:

- Reviewing the program's plan , responsibilities, organizational structure, staff (including educational background and experience), scope and description of the certification process, downgrading criteria and processes, and use of PE samples;
- Requesting an annual program report that includes program highlights, training, continuing education efforts, number of on-site evaluations performed, listing of laboratories certified by discipline or contaminant, and any certification downgrading or upgrading actions along with reasons for those actions;
- Observing on-site audits of drinking water laboratories to allow EPA Regional certification officers to evaluate specific elements of the State certification program;
- Encouraging State and Regional laboratory auditors to observe on-site audits of their own and other laboratories as on-the-job training;
- Sponsoring annual meetings of certification officers to discuss program issues, policies, and problems. Key Regional, NERL, and OGWDW and State personnel should be invited to participate.

Requirements for Certification of Laboratories

In order to be eligible to analyze compliance samples under the Safe Drinking Water Act, Regional and Principal State laboratories should meet the minimum criteria specified in this manual, should pass an on-site audit at least once every three years, and for chemistry must satisfactorily analyze a set of PE samples or other unknown test samples annually. EPA policy also requires that microbiology and radiochemistry laboratories also successfully analyze PE samples. For those laboratories certified for radiochemistry, satisfactory performance on additional PE samples may also be necessary.

Individual(s) Responsible for the Certification Program

NERL (Ci) and NERL (LV) are responsible for certifying the regional laboratories, the Regions are responsible for certifying their state laboratories, and the States are responsible for certifying private laboratories.

The certification program personnel in each Region should consist of the certification authority(s) (CA), the certification program manager(s), and a certification team comprised of certification officers (CO) and technical experts. Additional third party auditors and experts may be used. However, third parties must have no authority for certification decisions. Third party auditing is discussed in Appendix D.

The **Certification Authority (CA)** is the person who has signature authority for all certification decisions. This is the Director, NERL-Ci and NERL-LV and in the Regions, it is the Regional Administrator. The CA may delegate this authority to a lower level.

Each EPA Regional Administrator or designee should appoint, by memo, an individual to manage the drinking water laboratory certification activities in that Region. This person is the **Certification Program Manager**. This individual(s) should be experienced in quality assurance, hold at least a bachelor's degree or have equivalent experience in either microbiology, chemistry, radiochemistry or a related field and have sufficient administrative and technical stature to be considered a peer of the directors of the laboratories being audited. It is the responsibility of the certification program manager to assure that the Regional certification program meets the requirements of this manual.

40 CFR 142.10(b)(3)(i) requires Primacy States to designate a person certified by the Administrator as the official responsible for the State's certification program. This person would be the State certification authority.

On-Site Laboratory Audit Team

The certification program manager should establish one or more teams of certification officers and auditors to audit laboratories. It is the responsibility of these teams to perform the on-site laboratory audits, review the laboratory PE data and make recommendations to the CA concerning the certification status of the laboratories.

Team members should be experienced professionals, hold at least a bachelor's degree or equivalent education/experience in the discipline (chemistry, radiochemistry, microbiology or a related field) for which they certify, and have recent laboratory experience.

Team members should also have experience in laboratory evaluation and quality assurance, be familiar with the drinking water regulations and data reduction and reporting techniques, be technically conversant with the analytical techniques being evaluated and be able to communicate effectively, both orally and in writing.

The on-site team should include at least one CO knowledgeable in each area being audited (e.g., inorganic and organic chemistry, radiochemistry and microbiology). EPA policy requires COs to successfully complete the appropriate EPA laboratory certification course.

State certification programs may employ third party auditors who have passed the EPA certification officers' training course (see Appendix D) and meet all the qualifications listed above. Although these third parties may be used to assist the State certification officers, they may not make final certification decisions. These decisions rest with the State.

In areas where experience does not exist within the certification team (e.g., asbestos), outside expert assistance may be obtained in the needed areas to assist the on-site team. Outside experts who have not attended the EPA certification officer training must be accompanied by a certification officer. When using third party experts, it is critical to avoid conflicts of interest. A third party auditor who in any way stands to benefit by the certification status of the laboratory audited may not be used.

Plans for Certification of Laboratories

The certification authority should develop plans for certifying drinking water laboratories under her/his authority. Written plans should include the following:

- Documentation of certification authority and certification officers and their education/experience;
- Schedules of laboratories to be audited;
- Specific types of analyses to be examined;
- Protocol to be followed;
- Strategy for assessing laboratory performance (e.g., PEs, data audits, etc.);
- Plans for providing technical assistance to laboratories which need upgrading.

Principal State Laboratories

To receive and retain primacy, the State must have the availability of laboratory facilities certified by the EPA and capable of performing analytical measurements for all the contaminants specified in the State Primary Drinking Water Regulations. This laboratory or laboratories are considered the Principal State Laboratory and are certified by the Region either directly or through a reciprocal agreement.

Certification Process

The certification process begins when the laboratory director makes a formal request to the certification authority to be certified. This application may be one of the following:

- A request for first-time certification for microbiology, chemistry, or radiochemistry;

- A request for certification to analyze additional or newly regulated contaminants;
- A request to reapply for certification after correction of deficiencies which resulted in the downgrading/revocation of certification status.

The response to a formal application for any of the above requests should be given within 30 days. At this time a mutually agreeable date and time should be set for the on-site laboratory audit. The recommended protocol for conducting these audits is given in Appendix B. If this is not a first-time certification, an on-site visit may not be necessary.

Drinking water laboratories should verify that they plan to analyze drinking water samples when they request certification. If a laboratory has not been analyzing drinking water samples and does not plan to, the Region or State may choose not to renew their certification.

Types of Certification

After review of PE sample results and an on-site visit, the certification authority should provide a written report within 45 days and classify the laboratory for each contaminant or group of contaminants according to the following rating scheme:

- ***Certified*** - a laboratory that meets the minimum requirements of this manual and all applicable regulatory requirements. "Certified" status may not be granted to any laboratory that has not met performance criteria specified in the National Primary Drinking Water Regulations (NPDWR) and within the policy required by their certification authority.

- ***Provisionally Certified*** - a laboratory that has deficiencies but demonstrates its ability to consistently produce valid data within the acceptance limits specified in the NPDWR, and within the policy required by their certification authority. A provisionally certified laboratory may analyze drinking water samples for compliance purposes. Provisional certification may not be given if the evaluation team believes that the laboratory cannot perform an analysis within the acceptance limits specified in the regulations.

- ***Not Certified*** - a laboratory that possesses major deficiencies and, in the opinion of the Certification Authority, cannot consistently produce valid data within the acceptance limits specified in the NPDWR and within the policy described by their certification authority.

Interim Certification - interim certification may be granted in certain circumstances when it is impossible or unnecessary to perform an on-site audit. Interim certification status may be granted only when the CA judges that the laboratory has the appropriate instrumentation, is using the approved methods, has adequately trained personnel to perform the analyses, and has satisfactorily analyzed PE samples, if available, for the contaminants in question. PE samples from a commercial vendor may be used. The CO should perform an on-site audit as soon as possible but in no case later than three years. An example of a situation where this type of certification is warranted might be a laboratory that has requested certification for the analysis of additional analytes that involves use of a method for which it already has certification or a very similar method. The CO should review the laboratory's quality control data before granting this type of certification.

Primacy

Primacy States in which all drinking water compliance analyses are **not** conducted at State operated laboratories, are required to establish a certification program for drinking water laboratories [see 40 CFR 142.10(b)(3)(i)]. All States, however, are encouraged to develop such programs. EPA encourages the States to base certification of drinking water laboratories either upon criteria contained in this manual or upon state-developed equivalents that are at least as stringent as this manual. All state certification programs must require compliance with all provisions of the National Primary Drinking Water Regulations. Those states required by regulation to develop a certification program must designate "a laboratory officer or officers, certified by the [Regional] Administrator [or his or her designee], as the

official(s) responsible for the State's certification program." (40 CFR §142.10(3)(i)).

Drinking Water Laboratories

Any laboratory which analyzes drinking water compliance samples is considered a drinking water laboratory for the purpose of certification. This includes Federal laboratories that analyze compliance samples and other laboratories that analyze compliance samples for Federal facilities. **All** such laboratories must be certified by the State or EPA. If requested by the State, a Region may certify Federal laboratories in its Region.

The Region should certify individual laboratories on Federal Indian lands, if requested by the tribal chairperson. These laboratories must meet the same criteria for certification as specified in the NPDWR and this manual.

The criteria, procedures, and mechanism EPA uses to certify municipal or private drinking water laboratories are the same as those for principal state laboratories.

Other Considerations for Laboratory Certification

Laboratory Personnel

The laboratory should have sufficient supervisory and other personnel, with the necessary education, training, technical knowledge and experience for their assigned functions.

Laboratory Director/Manager or Technical Director

The laboratory director/manager should be a qualified professional with the technical education and experience and managerial capability commensurate with the size/type of the laboratory. The laboratory director/manager is ultimately responsible for ensuring that all laboratory personnel have demonstrated proficiency for their assigned functions and that all data reported by the laboratory meet the required quality assurance (QA) criteria and regulatory requirements.

Quality Assurance Officer/Manager

The QA officer/manager should be independent from the laboratory management if possible and have direct access to the highest level of management. The QA officer/manager should have a bachelor's degree in science, training in quality assurance principles commensurate with the size and sophistication of the laboratory and at least one year of experience in quality assurance/control. The QA officer/manager should have at least a working knowledge of the statistics involved in quality control of laboratory analysis and a basic understanding of the methods which the laboratory employs.

Laboratory Quality Assurance Plan

All laboratories analyzing drinking water compliance samples must adhere to the QC procedures specified in the methods. This is to ensure that routinely generated analytical data are scientifically valid and defensible and are of known and acceptable precision and accuracy. To accomplish these goals, each laboratory should prepare a written description of its QA activities (a QA plan). It is the responsibility of the QA manager to keep the QA plan up to date. All laboratory personnel must be familiar with the contents of the QA plan. This plan should be submitted to the auditors for review prior to the on-site visit or should be reviewed as part of the on-site visit.

The laboratory QA plan should be a separately prepared text. However, documentation for many of the listed QA plan items may be made by reference to appropriate sections of this manual, the laboratory's standard operating procedures, (SOPs) or other literature (e.g., promulgated methods, *Standard Methods for the Examination of Water and Wastewater*, etc.). The QA Plan should be updated as necessary.

At a minimum, the following items should be addressed in each QA plan:

1. Laboratory organization and responsibility
    - include a chart or table showing the laboratory organization and lines of responsibility, including QA

managers;
- list the key individuals who are responsible for ensuring the production of valid measurements and the routine assessment of measurement systems for precision and accuracy (e.g., who is responsible for internal audits and reviews of the implementation of the plan and its requirements);
- reference the job descriptions of the personnel and describe training to keep personnel updated on regulations and methodology, and document that laboratory personnel have demonstrated proficiency for the methods they perform.

2. Process used to identify clients' Data Quality Objectives
3. SOPs with dates of last revision
   - keep a list of SOPs
   - ensure that current copies of SOPs are in the laboratory and in the QA Managers files;
   - ensure that SOPs are reviewed annually and revised as changes are made;
   - ensure that SOPs have signature pages and revisions dated.
4. Field sampling procedures
   - describe the process used to identify sample collectors, sampling procedures and locations, required preservation, proper containers, correct sample container cleaning procedures, sample holding times from collection to analysis, and sample shipping and storage conditions;
   - ensure that appropriate forms are legibly filled out in indelible ink or hard copies of electronic data are available. See Chapters IV, V, and VI for specific items to be included;
   - describe how samples are checked when they arrive for proper containers and temperature and how samples are checked for proper preservation (e.g., pH, chlorine residual) before analysis;
   - ensure that sampling protocol is written and available to samplers.
5. Laboratory sample handling procedures
   - use bound laboratory note books, filled out in ink; entries dated and signed (A secure, password protected, electronic data base is acceptable);
   - store unprocessed and processed samples at the proper temperature, isolated from laboratory contaminants, standards and highly contaminated samples and, sometimes, each other; holding times may not be exceeded;
   - maintain integrity of all samples, (e.g., by tracking samples from receipt by laboratory through analysis to disposal);
   - require Chain-of-Custody procedures for samples likely to be the basis for an enforcement action (see Appendix A);
   - specify criteria for rejection of samples which do not meet shipping, holding time and/or preservation requirements and procedures for notification of sample originators.
6. Calibration procedures for chemistry and radiochemistry (may reference SOP)
   - specify type of calibration used for each method and frequency of use;
   - describe standards' source, age, storage, labeling;
   - perform data comparability checks;
   - use control charts and for radiochemistry, report counting errors with their confidence levels.
7. Analytical procedures (may reference SOP)
   - cite complete method manual;
   - describe quality control procedures required by the methods that must be followed.
8. Data reduction, validation, reporting and verification (may reference SOP)
   - describe data reduction process: method of conversion of raw data to mg/L, picocuries/L, coliforms/100 mL, etc.;
   - describe data validation process;
   - describe reporting procedures, include procedures and format;
   - describe data verification process;
   - for radiochemistry, describe reporting of counting uncertainties and confidence levels;
   - describe procedure for data corrections.
9. Type of quality control (QC) checks and the frequency of their use (see Chapters IV, V and VI).(may reference SOP)

Parameters for chemistry and radiochemistry should include or reference:

- instrument performance check standards;
- frequency and acceptability of method detection limit (MDL) calculations;
- calibration, internal and surrogate standards;
- laboratory reagent blank, field reagent blank and trip blank;
- field and laboratory matrix replicates;
- quality control and performance evaluation samples;
- laboratory fortified blank and laboratory fortified sample matrix replicates;
- initial demonstration of method capability and use of control charts;
- qualitative identification/confirmation of contaminants.

Parameters for microbiology should include or reference:

- positive and negative culture controls;
- confirmation/verification of presumptive total coliform positive samples;
- sterility controls;
- performance evaluation and quality control samples.

10. List schedules of internal and external system and data quality audits and inter laboratory comparisons (may reference SOP)
11. Preventive maintenance procedures and schedules
    - describe location of instrument manuals and schedules and documentation of routine equipment maintenance;
    - describe availability of instrument spare parts in the laboratory;
    - list any maintenance contracts in place.
12. Corrective action contingencies
    - describe response to obtaining unacceptable results from analysis of PE samples and from internal QC checks;
    - name persons responsible for the various corrective actions;
    - describe how corrective actions taken are documented;
13. Record keeping procedures
    - describe procedures and documentation of those procedures;
    - list length of storage, media type (electronic or hard copy);
    - describe security policy of electronic databases.

If a particular item is not relevant, the QA plan should state this and provide a brief explanation. A laboratory QA plan should be responsive to the above items while remaining brief and easy to follow. Minimizing paperwork, while improving dependability and quality of data, are the intended goals.

Performance on Routine Water Samples

Each certification authority should develop a strategy to assess laboratory performance on routine water samples as part of its certification program. This strategy may include one or more of the following approaches or some other approach: blind audit samples; analysis of an unknown sample during the on-site evaluation; a split sample program with the laboratory; a data audit; or observation of daily routine during an on-site visit. Each Certification Authority should develop a written plan that addresses this issue. The Regional plan is approved by OGWDW with NERL concurrence. The State plan is approved by the Region.

Chain-of-Custody Procedures

Certified laboratories, when requested to process a sample for possible legal action against a supplier, should use an adequate chain-of-custody procedure. An example of such a procedure is found in Appendix A. The State or Region should seek input from its attorney general's office to ensure that the laboratory's procedures are adequate. The procedure used should be documented.

Requirements for Maintaining Certification Status

Performance Evaluation (PE) Samples

All certified drinking water laboratories **must** satisfactorily analyze PE samples or other unknown test samples to maintain certification for inorganic and organic contaminants. Currently, the regulations stipulate that if a laboratory satisfactorily analyzes 80% of the regulated Volatile Organic Chemicals, it may be certified for all of them (except vinyl chloride which is certified separately). If the VOCs are provided in more than one vial, they must be considered collectively. However, it is recommended that a laboratory not be certified for a particular VOC which is unsatisfactorily analyzed two times in succession.

If the laboratory does not analyze the PE sample, or other unknown test sample, within the acceptance limits specified in the regulations, or within policy described by their certifying authority, the certifying authority must follow the procedure discussed in the section entitled, "Criteria and Procedures for Downgrading/Revoking Certification Status."

If a laboratory wishes to be certified for a contaminant by more than one method, it should analyze the PE samples by each method for which it wishes to be certified. If the PE provider cannot accommodate PE data by more than one method, the additional data should be submitted directly to the certification officer. The methods listed on the laboratory's certification certificate must be the methods by which the PE samples were analyzed.

The laboratory should be able to provide documentation to the certification authority that the person(s) analyzing any PE sample is a laboratory employee who routinely analyzes drinking water compliance samples.

To maintain certification in radiochemistry, NERL-LV requires laboratories to participate satisfactorily in the NERL-LV PE program.

Methodology
Laboratories must use the methods specified in the drinking water regulations at 40 CFR part 141 These methods are listed in Chapters IV, V, VI, and Appendix G.

Notification of Certifying Authority (CA) of Major Changes
Certified laboratories should notify the appropriate CA (Regional Administrator or designee or the appropriate NERL) **in writing**, within 30 days of major changes in personnel, equipment, or laboratory location. A major change in personnel is defined as the loss or replacement of the laboratory supervisor or a situation in which a trained and experienced analyst is no longer available to analyze a particular parameter for which certification has been granted. The CA should discuss the situation with the laboratory supervisor and establish a schedule for the laboratory to address major changes. If the CA determines that the laboratory can no longer produce valid data, the CA should follow the procedure for revocation of certification.

On-Site Evaluation
The CA should be satisfied that a laboratory is maintaining the required standard of quality for certification. Normally, this should be based on a recommendation from an on-site evaluation. If the laboratory undergoes a major change, however, or if it fails a PE sample or other unknown test sample, the CA should consider conducting an evaluation before the usual three year period has expired.

Criteria and Procedures for Downgrading/Revoking Certification Status

Criteria for Downgrading Certification Status
A laboratory should be downgraded to "provisionally certified" status for a contaminant or group of contaminants for any of the following reasons:

- Failure to analyze a PE sample at least annually within the acceptance limits specified in the regulations, or, if there are no requirements specified in the regulations, within policy described by their certifying authority;

- Failure of a certified laboratory to notify the CA within 30 days of major changes (e.g., in personnel,

equipment, or laboratory location);

- Failure to satisfy the CA that the laboratory is maintaining the required standard of quality, based upon an EPA on-site evaluation;

- Failure to report compliance data to the public water system or the State drinking water program in a timely manner, thereby preventing compliance with Federal or State regulations and endangering public health. Data which may cause the system to exceed an MCL should be reported as soon as possible.

Procedures for Downgrading to "Provisionally Certified" Status

If a laboratory is subject to downgrading on the basis of the above indicated criteria, the CA should notify the laboratory director or owner of its intent to downgrade (by registered or certified mail) within 14 days from becoming aware of the situation warranting downgrading. The laboratory director should review the problems cited and, within 30 days of receipt of the letter, send a letter to the CA specifying what immediate corrective actions are being taken and any proposed actions that need the concurrence of the CA. The CA should consider the adequacy of the response and notify the laboratory in writing (by registered or certified mail) of its certification status within 14 days of receipt of its response. The CA should follow up to ensure that corrective actions have been taken.

If a laboratory fails to analyze a PE or other unknown sample within the acceptance limits, the CA should not downgrade certification if the laboratory identifies and corrects the problem to the CA's satisfaction within 30 days of being notified of the failure. If, after a review of the submitted information, the CA determines that the laboratory need not be downgraded, then within 30 days of this decision, the CA should send the laboratory another unknown sample containing the failed contaminant. If the laboratory analyzes this second unknown sample within the acceptance limits established by the EPA or State (using the most recent PE summary statistical compilations), the laboratory should not be downgraded. If the laboratory fails to analyze this second unknown sample within the established limits, the CA should downgrade the laboratory to "provisionally certified" status and notify the laboratory within 14 days (by registered or certified mail). Laboratories should be downgraded only for the analyte failed, except where EPA/State certifies a group of related analytes based on a limited number of analytes in the group. (See "Periodic Performance Evaluation Samples" for additional information.)

During any phase of this procedure, a laboratory may request that the EPA or State provide technical assistance to help identify and resolve any problem.

Once the CA notifies a laboratory, in writing, that it has been downgraded to "provisionally certified" status for procedural, administrative, equipment or personnel deficiency, the laboratory should correct its problem within three months (six months for major equipment replacement). If the laboratory was downgraded to "provisionally certified" status because of a failure to analyze a PE sample (or other unknown test sample) within the acceptance limits specified in the regulations, or within policy required by their certifying authority, the laboratory should correct its problems and satisfactorily analyze another PE sample (or other unknown sample) within one month of receipt of the second PE sample. A provisionally certified laboratory may continue to analyze samples for compliance purposes, but should notify its clients of its downgraded status and provide that information, in writing, on any report.

Criteria for Revoking Certification Status

A laboratory shall be downgraded from certified, provisionally certified or interim certified status to "not certified" for a particular contaminant analysis for the following reasons:

- Submission of a PE sample to another laboratory for analysis and reporting the data as its own;
- Falsification of data or other deceptive practices;
- Failure to use the analytical methodology specified in the regulations;
- For provisionally certified laboratories, failure to successfully analyze a PE sample or any other unknown test sample for a particular contaminant within the acceptance limits specified;

- For provisionally certified laboratories, failure to satisfy the CA that the laboratory has corrected deviations identified during the on-site evaluations;
- For provisionally certified laboratories, persistent failure to report compliance data to the public water system or the State drinking water program in a timely manner thereby preventing compliance with Federal and/or State regulations and endangering public health. Data which may cause the system to exceed an MCL should be reported as soon as possible.

Procedures for Revocation

The CA should notify the laboratory, in writing (by registered or certified mail) of the intent to revoke certification. If the laboratory wishes to challenge this decision, a notice of appeal should be submitted in writing to the CA within 30 days of receipt of the notice of intent to revoke certification. If no notice of appeal is filed, certification shall be revoked.

The notice of appeal should be supported with an explanation of the reasons for the challenge and must be signed by a responsible official from the laboratory such as the president/owner for a commercial laboratory, or the laboratory supervisor in the case of a municipal laboratory or the laboratory director for a State or Regional laboratory.

Within 30 days of receipt of the appeal, the CA should make a decision and notify the laboratory in writing (by registered or certified mail). Denial of the appeal shall result in immediate revocation of the laboratory's certification. Once certification is revoked, a laboratory may not analyze drinking water samples for compliance until its certification has been reinstated.

If the appeal is determined to be valid, the CA should take appropriate measures to reevaluate the facility and notify the laboratory, in writing (by registered or certified mail), of its decision within 30 days of the reevaluation.

Reinstatement of Certification

Through a written request, a laboratory may seek reinstatement of certification, when and if the laboratory can demonstrate to the CA's satisfaction that the deficiencies which produced provisionally certified status or revocation have been corrected. This may include an on-site evaluation, successful analysis of unknown samples or any other measure the CA deems appropriate.

Reciprocity

Reciprocity, mutually acceptable certification among Regions and/or primacy States, is strongly endorsed by EPA as a highly desirable element in the certification program for drinking water laboratories. EPA also believes that use of a third party auditing agent by more than one State could promote reciprocity. (See Appendix D)

States are encouraged to adopt provisions in their laws and regulations to permit reciprocity. Even though ultimate responsibility for reciprocal certification resides with the Regions and primacy States, the States may ask for the assistance of EPA in cases involving clarification of what should be considered in a reciprocal agreement. Such requests should be submitted to the Region or OGWDW through the Region.

Training

Training is an integral part of the laboratory certification process for personnel conducting on-site evaluations of laboratories on behalf of either the Regional Office or a primacy State.

EPA policy requires that all Regional certification officers must initially pass the appropriate EPA laboratory certification training courses for the discipline for which they certify (chemistry, radiochemistry or microbiology). All laboratory auditors should be experienced professionals and have at least a bachelor's degree or equivalent education/experience in the discipline for which they certify and recent laboratory experience in the field for which they audit laboratories. Third party auditors (see Appendix D) must also pass the EPA certification training course. Outside experts, retained for their knowledge in a limited area (e.g., asbestos) are not required to pass the laboratory

certification course if they are used as part of an on-site audit team which includes a certification officer. Periodic training for both laboratory auditors and analysts should be provided by the Regions. Certification officers should attend refresher training programs at least every five years to keep their knowledge of the methods and the drinking water program current. It is highly recommended that certification officers have recent bench experience in the methods for which they certify. OGWDW will notify certification officers of major updates/changes to EPA's certification program. It is recommended that the States use these same criteria in their certification programs.

Alternate Analytical Techniques

EPA approves analytical methods for all regulated drinking water contaminants. A regulation for a particular contaminant will include approval of one or more methods that must be used to determine that contaminant. Subsequent to publishing a rule (promulgation), the Agency may approve new methods or modifications of EPA approved methods through another rule.

"With the written permission of the State, concurred in by the Administrator of the US EPA, an alternate analytical technique may be employed. An alternate technique shall be accepted only if it is substantially equivalent to the prescribed test in both precision and accuracy as it relates to the determination of compliance with any MCL."(CFR 141.27(a)

Anyone can request that EPA approve a new method or modification of a method already approved by EPA, by submitting EPA-specified data and other information to the Director, Analytical Methods Staff, Office of Science and Technology (MS4303), Office of Water, USEPA, 401 M Street, SW, Washington DC 20460. EPA will evaluate the material to determine whether the method meets EPA criteria. If a method meets the specified criteria, it will be approved. This involves a formal proposal in the Federal Register, public comment, and finally (unless otherwise indicated by the public comments or other new information), promulgation in the Federal Register. Once approved (i.e., promulgated), any laboratory may use the method.

Chapter IV
Critical Elements for Chemistry

1. Personnel

1.1 Laboratory Supervisor

The laboratory supervisor should have at least a bachelor's degree with a major in chemistry or equivalent and at least one year of experience in the analysis of drinking water. The laboratory supervisor should have at least a working knowledge of quality assurance principles. The laboratory supervisor has immediate responsibility to insure that all laboratory personnel have demonstrated their ability to satisfactorily perform the analyses to which they are assigned and that all data reported by the laboratory meet the required quality assurance and regulatory criteria.

1.2 Laboratory Analyst

The laboratory analyst should have at least a bachelor's degree with a major in chemistry or equivalent and at least one year of experience in the analysis of drinking water. If the analyst is responsible for the operation of analytical instrumentation, he or she should have completed specialized training offered by the manufacturer or another qualified training facility or served a period of apprenticeship under an experienced analyst. The duration of this apprenticeship is proportional to the sophistication of the instrument. Data produced by analysts and instrument operators while in the process of obtaining the required training or experience are acceptable only when reviewed and validated by a fully qualified analyst or the laboratory supervisor.

Before beginning the analysis of compliance samples, the analyst must demonstrate acceptable results for blanks, precision, accuracy, method detection and specificity and satisfactory analysis on unknown samples.

1.3 Technician

The laboratory technician should have at least a high school diploma or equivalent, complete a method training program under an experienced analyst and have six months bench experience in the analysis of drinking water samples.

Before beginning the analysis of compliance samples, the technician must demonstrate acceptable results for blanks, precision, accuracy, method detection and specificity and satisfactory analysis on unknown samples.

1.4 Sampling Personnel

Personnel who collect samples should have been trained in the proper collection technique for all types of samples which they collect. Their technique should be reviewed by experienced sampling or laboratory personnel.

1.5 Waiver of Academic Training Requirement

The certification officer may waive the need for specified academic training, on a case-by-case basis, for highly experienced analysts.

Training records should be maintained for all personnel. These should include all job related formal training taken by the analyst which pertains to any aspect of his/her responsibilities, including but not limited to analytical methodology, laboratory safety, sampling, quality assurance, data analysis, etc.

2. Laboratory Facilities

The analysis of compliance samples should be conducted in a laboratory where the security and integrity of the samples and the data can be maintained. The laboratory facilities should be clean, have adequate temperature and humidity control, have adequate lighting at the bench top and must meet applicable OSHA standards. The laboratory must have provisions for the proper storage and disposal of chemical wastes. The appropriate type of exhaust hood is required where applicable.

There should be sufficient bench space for processing samples. Workbench space should be convenient to sink, water, gas, vacuum and electrical sources free from surges. Instruments should be properly grounded. For safety reasons,

inorganic and organic facilities should be in separate rooms; organic analysis and sample extraction should also be separated to prevent cross contamination. The analytical and sample storage areas should be isolated from all potential sources of contamination. There should be sufficient storage space for chemicals, glassware and portable equipment, sufficient floor and bench space for stationary equipment and areas for cleaning materials.

3. Laboratory Equipment and Instrumentation

The laboratory must have the instruments and equipment needed to perform the approved methods for which certification has been requested. The checklist on page 43 of this chapter provides more information on the necessary equipment. All instruments should be properly maintained and calibrated.

4. General Laboratory Practices

4.1 General

4.1.1 Chemicals/reagents: Chemicals and reagents used must meet the specifications in the method. If not specified, then "Analytical reagent grade" (AR) or American Chemical Society (ACS) grade chemicals or better should be used for analyses in certified laboratories. Consult *Standard Methods for the Examination of Water and Wastewater, 18th Edition*, part 1070 for more detailed information on reagent grades.

4.2 Inorganic Contaminants

4.2.1 Reagent water: The laboratory should have a source of reagent water having a resistance value of at least 0.5 megohms (conductivity less than 2.0 micromhos/cm) at 25°C. High quality water meeting such specifications may be purchased from commercial suppliers. Quality of reagent water is best maintained by sealing it from the atmosphere. Quality checks to meet specifications above should be made and documented at planned intervals based on use. This planned interval should not exceed one month. Individual analytical methods may specify additional requirements for the reagent water to be used.

4.2.2 Glassware preparation: Specific requirements in the methods for the cleaning of glassware must be followed. If no specifications are listed, then glassware should be washed in a warm detergent solution and thoroughly rinsed first with tap water and then with reagent water. This cleaning procedure is sufficient for general analytical needs. It is advantageous to maintain separate sets of suitably prepared glassware for the nitrate, mercury, and lead analyses due to the potential for contamination from the laboratory environment. Refer to Table IV-1 for a summary of glassware cleaning procedures.

4.3 Organic Contaminants

4.3.1 Reagent water: Reagent water for organic analysis must be free from interferences for the analytes being measured. It may be necessary to treat water with activated carbon to eliminate all interferences. If individual methods specify additional requirements for the reagent water to be used, these must be followed.

4.3.2 Glassware preparation: Glassware cleaning requirements specified in the methods must be followed. Table IV-1 summarizes the cleaning procedures specified in the EPA methods.

4.4 Laboratory safety

While safety criteria are not an aspect of laboratory certification, laboratory personnel should apply general and customary safety practices as a part of good laboratory practices. Each laboratory is encouraged to have a safety plan as part of their standard operating procedure which includes personnel safety, training and protection. Where safety practices are included in an approved method (i.e., 515.1), they must be followed. See *Standard Methods for the Examination of Water and Wastewater*, part 1090 for a discussion of laboratory safety.

4.5 Quality Assurance

Laboratories should maintain current Quality Assurance Plans as described in Chapter 3. All laboratory activities including sampling, test methods, instrument operation, data generation and corrective action should be described in the Plan. Plans should be available to all personnel.

5. Analytical Methods

5.1 General

A list of approved methods for inorganic and organic contaminants can be found in Tables IV-2 and IV-3, respectively. Methods manuals should be available in-house. Allowed modification to the methods should be documented. All procedural steps in these methods are considered requirements. Other methods cannot be used for compliance samples unless approval has been granted by the Agency. Contact the appropriate certifying authority for an alternate test procedure application. Application for the use of an alternate method may require acceptable comparability data. Table IV-4 lists the methods which must be used for contaminants which are regulated for monitoring only (have no MCLs). Table IV-5 lists the methods which must be used for the analysis of disinfectants. Recommended methods for Secondary contaminants are listed in Table IV-6. For more information, see Appendix H, section 2.1

5.2 Analyses approved by the State

Measurements for turbidity, pH, temperature, residual disinfectant, calcium, orthophosphate, silica, alkalinity, and conductivity need not be made in certified laboratories, but may be performed by any persons acceptable to the State. However, approved methodology must be used (Tables IV-2-5). The State should institute a quality assurance program to assure validity of data from these measurements.

5.2.1 Turbidity standards: Sealed liquid turbidity standards purchased from the instrument manufacturer should be calibrated against properly prepared and diluted formazin or styrene divinylbenzene polymer standards at least every four months in order to monitor for any eventual deterioration. This calibration should be documented. These standards should be replaced when they do not fall within 15% of the concentration of the standard. Solid turbidity standards composed of plastic, glass, or other materials are not reliable and should not be used.

5.2.2 Residual chlorine standards: If visual comparison devices such as color wheels or sealed ampules are used for determining free chlorine residual, the standards incorporated into such devices should be calibrated at least every six months. These calibrations should be documented. Directions for preparing temporary and permanent type visual standards can be found in Method 4500-Cl-G, of *Standard Methods for the Examination of Water and Wastewater*, 18th Edition, 1992. By comparing standards and plotting such a comparison on graph paper, a corrective factor can be derived and applied to future results obtained on the now calibrated apparatus.

6. Sample Collection, Handling, and Preservation

The manner in which samples are collected and handled is critical to obtaining valid data. It is important that a written sampling protocol with specific sampling instructions be available to and used by sample collectors and available for inspection by the certification officer. (Appendix A, Chain-of-Custody).

6.1 Rejection of Samples

The laboratory must reject any sample taken for compliance purposes which does not meet the criteria in 6.2 through 6.6 and notify the authority requesting the analyses. See Appendix H section 1.3.

6.2 Sample Containers and Preservation

The type of sample container and the required preservative for each inorganic and organic chemical contaminant are listed in Table IV-7. The use of "blue ice" is discouraged because it generally does not maintain the temperature of the sample at 4C or less. If blue ice is used, it should be frozen at the time of sampling, the sample should be chilled before packing, and special notice must be taken at sample receipt to be certain the required temperature (4C) has been maintained.

6.3 Maximum Holding Times

Samples must be analyzed within the maximum holding times listed in Table IV-7.

6.4 Sample Collection and Transport

There must be strict adherence to correct sampling procedures, complete identification of the sample, and prompt

transfer of the sample to the laboratory. When the laboratory is not responsible for sample collection and transport, it must verify that the paperwork, preservatives, containers and holding times are correct or reject the sample. For more information, see Appendix H, section 1.0.

6.5 Sample Collector

The sample collector should be trained in sampling procedures and have complete written sampling instructions (SOPs) for each type of sample to be collected. The sampler should be able to demonstrate proper sampling technique.

6.6 Sample Report Form

The sample report form should contain the ID, location, date and time of collection, collector's name, preservative added and shipping requirements, container and volume, sample type, analysis, and any special remarks concerning the sample. Indelible ink should be used. See Appendix H, section 1.1.

6.7 Sample Compositing

Compositing of samples for inorganic and organic analyses must be done in the laboratory. Samples should only be composited if the laboratory detection limit is adequate for the number of samples being composited (up to a maximum of five) and the holding times will not be exceeded.

7. Quality Control

Additional information is contained in Appendix H. Specific items are referenced throughout.

7.1 General Requirements

7.1.1 Availability of QC Information: All quality control information should be available for inspection by the certification officer.

7.1.2 Standard Operating Procedures: A manual of analytical methods and the laboratory's QA plan and Standard Operating Procedures (SOPs) should be readily available to the analysts (see Chapter III's discussion of Quality Assurance).

7.1.3 Balances and Weights: Balance range should be appropriate for the application for which it is to be used. Drinking water chemistry laboratories should use balances that weigh to at least 0.0001 g. The balances should be calibrated at least annually with ASTM Type I, Class 1 or 2 weights. (ASTM, 1916 Race St.., Philadelphia, PA 19103) This may be done by laboratory personnel or under contract by a manufacturer's representative. We strongly recommend laboratories have a contract to calibrate balances due to the expense of the weights and to serve as an outside QC check of the weights and balances. Weights meeting ASTM Type I, Class 1 or 2 specifications should be recertified if there is reason to believe damage (corrosion, nicks) has occurred or at least every five years.

Laboratory personnel should perform at least weekly checks of the balance. Weights meeting ASTM Type 1 specifications may be used but should be calibrated annually against the reference weights at time of balance calibration. A record of all checks should be available for inspection. The checks and their frequency should be as prescribed in the laboratory's QA Plan.

7.1.4 Color Standards: Wavelength settings on spectrophotometers should be verified each day they are used with color standards. A record of these checks should be available for inspection. The specific checks and their frequency should be as prescribed in the SOPs.

7.1.5 Thermometers: Thermometers should be traceable to ASTM calibration and recertified whenever the thermometer has been exposed to temperature extremes.

7.1.6 Traceability of Calibration: Calibrations of all measurement devices should be traceable to national

standards whenever applicable.

7.2 Specific Requirements: The following are required for each analyte for which a laboratory is certified:

7.2.1 Performance Evaluation Samples: The laboratory must analyze performance evaluation samples (if available) acceptable to the Certifying Authority at least once per year in order to receive and maintain full certification for an analyte. Results from analysis of the performance evaluation sample must be within the acceptable limits established by U.S. EPA. These acceptance limits are listed in Table IV-9. The laboratory should document the corrective actions taken when a PE sample is missed. A copy of this documentation should be forwarded to the certification officer. A make up PE sample must be successfully analyzed. If problems arise, appropriate action must be taken as specified in Chapter III, Implementation of Certification Program. See Appendix H, section 2.5.6

For VOCs, the laboratory may be certified for all VOCs (except vinyl chloride) or for the VOC method if they successfully analyze at least 80% of the regulated VOCs. The intention of the regulation was to allow some flexibility for random misses because the VOC methods include 20 analytes. The intention is not to allow a laboratory to be certified for an analyte which it misses repeatedly.

7.2.2 Quality Control Samples: At least once each quarter, the laboratory should analyze a quality control standard for the analytes they are analyzing in that quarter. The check standard should be prepared from a source other than that from which their standards are prepared. If errors exceed limits specified in the methods, corrective action must be taken and documented, and a follow-up quality control standard analyzed as soon as possible to demonstrate the problem has been corrected.

7.2.3 Calibration Curve: Calibration requirements in the methods must be followed. If there are none, these are some guidelines to follow. At the beginning of each day that samples are to be analyzed, a calibration curve covering the sample concentration range and all target analytes should be generated according to the approved SOP. The curve should be composed of at least three concentrations, although some methods recommend that five concentrations be included. Some inorganic methods require at least a blank and three concentrations for each analyte. The calibration standards should be from a source different from the quality control standard used for 7.2.2. Field measurements (e.g., pH and chlorine residual) should also be made on instruments which have been properly calibrated as specified in the method or instrument manual and checked daily. The less precise the measurement, the greater the number of concentrations which should be included in the calibration curve. EPA gas chromatography methods recommend using five standards. See Appendix H, section 2.3.1.

7.2.4 Calibration Check: The calibration for some methods is so time-consuming that 7.2.3 is impractical. For these methods, the calibration curve should be initially developed as specified in 7.2.3. Thereafter, at the beginning of each day on which analyses are performed, this curve should be verified by analysis of at least a reagent blank and one standard for each of the target analytes in the expected concentration range of the samples analyzed that day. All checks must be within the control limits specified in the method or the system recalibrated as specified in 7.2.3.

It is recommended that a calibration standard of one multicomponent analyte (PCBs, toxaphene and chlordane) also be analyzed each day or work shift. By rotating the analyte chosen, continuing calibration data can be obtained on all the multicomponent analytes over a period of one to two weeks. If a positive for a multi- component analyte is found in a sample, a calibration check for that analyte should be performed as soon as possible. Calibration requirements in the methods must be followed if different. See Appendix H, section 2.4.

7.2.5 Blanks: A laboratory reagent blank should be carried through the full analytical procedure with every sample batch. In general, results from laboratory reagent blanks should not exceed the laboratory's

method detection limit (MDL); see Section 7.2.8 and Appendix H, Section 2.5.4.

7.2.6 Laboratory Fortified Sample Matrix: The laboratory should add a known quantity of analytes to a minimum of 10% of the routine samples (except when the method specifies a different percentage, e.g., furnace methods or none as in 524.2) to determine sample matrix interference. The fortified concentration should not be less than the background concentration of the sample selected for fortification unless specified by the method. If the sample concentration is unknown or less than detectable, the analyst should choose an appropriate concentration (e.g., a percentage of the MCL or mid point in the calibration range). **Over time, samples from all routine sample sources should be fortified as much as is practical.** If any of these checks are not within the control limits specified in 7.2.7, and the laboratory performance is in control, the result for that sample must be labeled to inform the data user that the results are suspect due to matrix effects. See Appendix H, section 2.5.2.

7.2.7 Control Charts: Control charts, generated from laboratory fortified blanks (LFBs) should be maintained by the laboratory. Until sufficient data are available from the laboratory, usually a minimum of 20 to 30 test results on a specific analysis, the laboratory should use the control limits (if specified) in the methods.

When sufficient data become available, the laboratory should develop FRB control charts from the mean percent recovery ($\bar{x}$) and the standard deviation (S) of the percent recovery for the QC checks specified above (see Chapter VI of the *Handbook for Analytical QC in Water and Wastewater Laboratories*, EPA-600/4-79-019 or *Standard Methods for the Examination of Water and Wastewater*, part 1020B, or similar QC reference texts for further information). These data are used to establish upper and lower control limits as follows:

upper control limit = $\bar{x}$ + 3S (upper warning limit + 2S)
lower control limit = $\bar{x}$ - 3S (lower warning limit - 2S)

After each five to ten new recovery measurements, new control limits should be calculated using the most recent 20-30 data points. These calculated control limits should not exceed those established in the method. If any of these control limits are tighter than the method specifications, the laboratory should use the tighter criteria.

7.2.8 Initial Demonstration of Capability: Before beginning the analysis of compliance samples, an initial demonstration of capability (IDC) must be performed for each method. It is recommended that an IDC be performed for each analyst and instrument. In addition, it is recommended that the IDC also address the variability introduced if more than one sample preparation technician is used. Precision, accuracy and MDL should be similar for each technician. The IDC includes a demonstration of the ability to achieve a low background, the precision and accuracy required by the method, the method detection limit (MDL) in accordance with the procedure given in 40 CFR 136, Appendix B and satisfactory performance on an unknown sample. This definition is more encompassing than the definition of IDC in the methods. The IDC should be redone if there is a change in analyst, instrument or a significant change in the method. Minor changes should prompt a check to ascertain that the precision, accuracy and sensitivity have been maintained.

7.2.9 Quantitation of Multicomponent Analytes (toxaphene, chlordane and PCBs) The quantitation of multi- component analytes requires professional judgment on the part of the analyst. This is required due to the complex nature of the chromatography involved, sample weathering and degradation and interferences that may be present in the samples. The pattern of peaks found in the sample should be examined carefully and compared to a standard. The peaks in the sample that match the peak ratios in the standard can be used in quantitation. Peaks that have obvious interferences (such as pesticides or phthalates or peaks exhibiting

poor peak shape) or appear to have been degraded or weathered should not be used for quantitation. A representative number (5-9) of peaks is suggested. Peak area should be used for quantitation and the analyst should ensure that the samples and standards have been integrated in the same manner. Quantitation can be done by using the total peak area (comparing the area of the 5-9 peaks used for quantitation of the sample to the area of the standard) or by calculating each peak separately (using area) and taking the average concentration of the 5-9 peaks. Because of factors such as peak shape and baseline rise, the most accurate quantitation is obtained when the concentration of the sample closely matches that of the standard (e.g., within 20% of the standard). See EPA Method 8081, Organochlorine Pesticides and PCBs as Aroclors by Gas Chromatography: Capillary Column Technique, for a more detailed discussion of quantitation of multicomponent analytes.

Note: PCBs are qualitatively identified as Aroclors and measured for compliance purposes as decachlorobiphenyl. Chlordane is regulated as technical chlordane, a mixture of at least 11 major components and 30 minor ones.

7.2.10 Periodic MDL Calculation: Method detection limit calculations are required by regulation for VOCs, lead and composited samples. Table IV-8 lists the MDL requirements in the drinking water regulations. The CFR requires that a method detection limit of 0.0005 mg/L be attained for VOCs. For inorganics, a method detection limit of 1/5 of the MCL must be attained for compositing. Otherwise, the MCL is the required detection limit for inorganics. For SOCs, the detection limits listed in the CFR must be attained for compositing, but are currently not required for certification. This is somewhat contradictory, because the detection limits listed are the required monitoring triggers. Most methods require initial MDL calculations for all analytes. It is therefore recommended that the certification officers require the laboratories to calculate their detection limits for all regulated contaminants until a change is made in the regulation. See Appendix H, section 2.3 for more guidelines on MDLs.

It is recommended that sample preparation and analyses for the MDL calculation be made over a period of at least three days to provide a more realistic MDL. The analyst should recalculate MDLs when a significant change in the method, analyst or instrument is made which would affect the MDL. In addition, the analyst should regularly check the MDLs by analyzing laboratory fortified blanks at the same level as those that were used to calculate the MDL.

The calculation of MDLs by the CFR procedure may not be adequate for Aroclors, toxaphene and chlordane because they require pattern or peak profile recognition for identification. Presently, no standard procedure exists, so it is recommended that the MDL be defined as the lowest concentration for which pattern recognition is possible.

7.2.11 Low Level Quantitation: The laboratory's detection limits should be reported to the client along with the data. Many laboratories are uneasy reporting all detections above their MDLs because they realize that statistically, contaminants present at the MDL concentration may be missed 50% of the time. Also, contaminants may be reported which cannot be confirmed by a second technique. Laboratories may prefer not to report contaminants at levels less than two to three times their MDL or below the level at which they routinely analyze their lowest standard. While this may be a scientifically sound practice, whether it is an acceptable practice will depend on State and Federal reporting requirements. It is important for users of data to understand the statistical and qualitative significance of the data. Laboratories may be required by the States to achieve a specific MDL or quantitation limit more stringent than that required by EPA.

7.2.12 Laboratory Fortified Blanks: The analyst should routinely verify the reporting limit (if one is used) for each analyte by analyzing a laboratory fortified blank at the reporting level. In addition, most methods require that a laboratory fortified blank be analyzed with each batch of samples at ten times the MDL or a mid level standard. Precision and accuracy data must be documented for this determination.

7.2.13 Qualitative Identification: The analyst should also verify at what concentration specificity (qualitative identification/confirmation) can be determined (e.g., a spectrum should be identifiable or second column confirmation should be possible).

8. Records and Data Reporting

8.1 Legal Defensibility: Compliance monitoring data should be made legally defensible by keeping thorough and accurate records. The QA plan and/or SOPs should describe the policies and procedures used by the facility for record retention and storage. If samples are expected to become part of a legal action, chain of custody procedures should be used (See Appendix A).

8.2 Maintenance of Records: Public Water Systems are required to maintain records of chemical analyses of compliance samples for 10 years (40 CFR 141.33) and lead and copper for 12 years (40 CFR 141.91). The laboratory should maintain easily accessible records for five years or until the next certification data audit is complete, whichever is longer. The client water system should be notified before disposing of records so they may request copies if needed. This includes all raw data, calculations, and quality control data. These data files may be either hard copy, microfiche or electronic. Electronic data should always be backed up by protected tape or disk or hard copy. If the laboratory changes its computer hardware or software, it should make provisions for transferring old data to the new system so that it remains retrievable within the time frames specified above. Data which is expected to become part of a legal action will probably need to be maintained for a longer period of time. Check with your legal counsel. See Appendix H, section 3.0, and *Good Automated Laboratory Practices*, EPA 2185, Office of Information Management, Research Triangle Park, NC 27711, 8/10/95.

8.3 Sampling Records: Data should be recorded in ink with any changes lined through such that original entry is visible. Changes should be initialed and dated. The following information should be readily available in a summary or other record(s):

8.3.1 Date, location (including name of utility and PWSS ID #), site within the system, time of sampling, name, organization and phone number of the sampler, and analyses required;

8.3.2 Identification of the sample as to whether it is a routine distribution system sample, check sample, raw or finished water sample, repeat or confirmation sample or other special purpose sample;

8.3.3 Date of receipt of the sample;

8.3.4 Sample volume/weight, container type, preservation and holding time and condition on receipt;

8.3.5 pH and disinfectant residual at time of sampling (from plant records);

8.3.6 Transportation and delivery of the sample (person/carrier, conditions).

8.4 Analytical Records Data should be recorded in ink with any changes lined through such that original entry is visible. Changes should be initialed and dated. The following information should be readily available:

8.4.1 Laboratory and persons responsible for performing analysis;

8.4.2 Analytical techniques/methods used;

8.4.3 Date and time of analysis;

8.4.4 Results of sample and quality control analyses;

8.4.5 Calibration and standards information.

8.5 Personnel Records:
Resumes and training records should be maintained for all personnel. Analyst and technician Initial Demonstration of Capability documentation should be kept on file as well as results of proficiency testing.

8.6 Reconstruction of Data: Adequate information should be available to allow the auditor to reconstruct the final results for compliance samples and performance evaluation samples. See Appendix H.

8.7 Computer programs: Computer programs should be verified initially and periodically by manual calculations and the calculations should be available for inspection. Access to computer programs and electronic data should be limited to appropriate personnel.

9. Action Response to Laboratory Results

When a laboratory is responsible, either by contract or State policy, to report sample results which would cause a system to be out of compliance, the proper authority should be promptly notified and a request should be made for resampling from the same sampling point immediately. See Chapter III.

Table IV-1 Glassware Cleaning Procedures - consult the method for complete details; do not over heat volumetric glassware

Method	Washing	Drying
502.2/504/504.1/524.2	Detergent wash, rinse with tap and distilled water	105°C for 1 hour
505	Detergent wash, rinse with tap and reagent water	400°C for 1 hour or rinse with acetone
506	Rinse immediately with last solvent used, wash with hot water and detergent, rinse with tap and reagent water	400°C for 1 hour or rinse with acetone
507/508	Rinse immediately with last solvent used, wash with hot water and detergent, rinse with tap and reagent water	400°C for 1 hour or rinse with acetone
508.1	Detergent wash, rinse with tap and reagent water or solvent rinse	400°C for 2 hours
508A	no specifications, suggest the same as 515.1/515.2	no specification, suggest the same as 515.1/515.2
509	Detergent wash, rinse with tap and reagent water	105°C for 1 hour for septa, 400°C for 1 hour for vials
515.1/515.2	Rinse immediately with last solvent used, wash with hot water and detergent, rinse with dilute acid, tap and reagent water	400°C for 1 hour or rinse with acetone
525.2	Detergent wash, rinse with tap and distilled water or solvent rinse	air dry or muffle(no specs) (suggest 400°C for 1 hour)
531.1/6610	Rinse immediately with last solvent used, wash with hot water and detergent, rinse with tap and reagent water	450°C for 1 hour or rinse with acetone
547/548.1	Rinse immediately with last solvent used, wash with hot water and detergent, rinse with tap and reagent water	400°C for several hours or rinse with methanol

Method	Washing	Drying
549.1	Rinse immediately with last solvent used, wash with hot water and detergent, rinse with tap and reagent water	130°C for several hours or rinse with methanol
550/550.1	Rinse immediately with last solvent used, wash with hot water and detergent, rinse with tap and reagent water	400°C for 15-30 minutes or rinse with acetone or pesticide quality hexane
1613	Rinse with solvent, sonicate with detergent for 30 minutes, rinse sequentially with methanol, hot tap water, methanol, acetone and methylene chloride	Air dry
Metals	Wash with detergent, rinse with tap water, soak 4 hours in 20% (V/V) nitric acid or dilute nitric(~8%)/ hydrochloric(~17%), rinse with reagent water	Air dry
Inorganics	Wash with detergent, rinse with tap and reagent water (use phosphate free detergent for o-phosphate analysis)	Air dry

Table IV-2 Approved Methods for Primary Inorganic Chemicals, Parameters in the Lead and Copper Rule, Sodium, and Turbidity [§141.23(k)(1)]

Contaminant	Methodology	EPA	ASTM[3]	SM[4]	Other
Antimony	ICP-MS	200.8[2]			
	Hydride-AA		D3697-92		
	AA-Platform	200.9[2]			
	AA-Furnace			3113B	
Arsenic	ICP	200.7[2]		3120B	
	ICP-MS	200.8[2]			
	AA-Platform	200.9[2]			
	AA-Furnace		D2972-93C	3113B	
	Hydride-AA		D2972-93B	3114B	
Asbestos	TEM	100.1[9]			
	TEM	100.2[10]			
Barium	ICP	200.7[2]		3120B	
	ICP-MS	200.8[2]			
	AA-Direct			3111D	
	AA-Furnace			3113B	
Beryllium	ICP	200.7[2]		3120B	
	ICP-MS	200.8[2]			
	AA-Platform	200.9[2]			
	AA-Furnace		D3645-93B	3113B	
Cadmium	ICP	200.7[2]			
	ICP-MS	200.8[2]			
	AA-Platform	200.9[2]			
	AA-Furnace			3113B	
Chromium	ICP	200.7[2]		3120B	
	ICP-MS	200.8[2]			
	AA-Platform	200.9[2]			
	AA-Furnace			3113B	

Contaminant	Methodology	EPA	ASTM[3]	SM[4]	Other
Cyanide	Man. Distillation followed by:			4500-CN-C	
	Spec., Amenable		D2036-91B	4500-CN-G	
	Spec.Manual		D2036-91A	4500-CN-E	I-3300-85[5]
	Semi-auto	335.4[6]			
	Ion Sel. Elec.(ISE)			4500CN-F	
Fluoride	Ion Chromatography	300.0[6]	D4327-91	4110B	
	Manual Distill. SPADNS			4500F-B,D	
	Manual ISE		D1179-93B	4500F-C	
	Automated ISE				380-75WE[11]
	Auto. Alizarin			4500F-E	129-71W[11]
Mercury	Manual Cold Vapor	245.1[2]	D3223-91	3112B	
	Auto. Cold Vapor	245.2[1]			
	ICP-MS	200.8[2]			
Nitrate	Ion Chromatography	300.0[6]	D4327-91	4110B	B-1011[8]
	Auto Cd Reduction	353.2[6]	D3867-90A	4500-NO_3-F	
	Ion Selective Elec.			4500-NO_3-D	601[7]
	Man Cd Reduction		D3867-90B	4500-NO_3-E	
Nitrite	Ion Chromatography	300.0[6]	D4327-91	4110B	B-1011[8]
	Auto Cd Reduction	353.2[6]	D3867-90A	4500-NO_3-F	
	Man Cd Reduction		D3867-90B	4500-NO_3-E	
	Spectrophotometric			4500-NO_2-B	
Selenium	Hydride-AA		D3859-93A	3114B	
	ICP-MS	200.8[2]			
	AA-Platform	200.9[2]			
	AA-Furnace		D3859-93B	3113B	
Thallium	ICP-MS	200.8[2]			
	AA-Platform	200.9[2]			

Contaminant	Methodology	EPA	ASTM[3]	SM[4]	Other
Lead	AA-Furnace		D3559-90D	3113B	
	ICP-MS	200.8[2]			
	AA-Platform	200.9[2]			
Copper	AA-Furnace		D1688-90C	3113B	
	AA-Direct		D1688-90A	3111B	
	ICP	200.7[2]		3120B	
	ICP-MS	200.8[2]			
	AA-Platform	200.9[2]			
pH	Electrometric	150.1[1]	D1293-84	4500-H^+-B	
		150.2[1]			
Conductivity	Conductance		D1125-91A	2510B	
Calcium	EDTA titration		D511-93A	3500-Ca-D	
	AA-Direct		D511-93B	3111B	
	ICP	200.7[2]		3120B	
Alkalinity	Titration		D1067-92B	2320B	
	Elec. titration				I-1030-85[5]
Ortho-phosphate unfiltered, no digestion or hydrolysis	Color, automated ascorbic acid	365.1[6]		4500-P-F	
	Color, ascorbic acid		D515-88A	4500-P-E	
	Color, phosphomolybdate				I-1601-85[5]
	AutoSegmented Flow				I-2601-90[5]
	Auto discrete				I-2598-85[5]
	Ion Chromatography	300.0[6]	D4327-91	4110	

Contaminant	Methodology	EPA	ASTM[3]	SM[4]	Other
Silica	Color, molybdate blue;				I-1700-85[5]
	auto seg. flow				I-2700-85[5]
	Color		D859-88		
	Molybdosilicate			4500-Si-D	
	Heteropoly blue			4500-Si-E	
	Auto. molybdate reactive silica			4500-Si F	
	ICP	200.7[2]		3120B	
Temperature	Thermometric			2550B	
Sodium	ICP	200.7[2]			
	AA-Direct			3111B	
Turbidity	Nephelometric[6]	180.1		2130B	GLI Method 2[12]

FOOTNOTES

1 Methods 150.1, 150.2 and 245.2 are available from US EPA, EMSL, Cincinnati, OH 45268. The identical methods were formerly in "Methods for Chemical Analysis of Water and Wastes," EPA-600/4-79-020, March 1983.

2 "Methods for the Determination of Metals in Environmental Samples - Supplement I," EPA-600/R-94-111, May 1994. Available at NTIS, PB 94-184942.

3 *Annual Book of ASTM Standards*, Vols. 11.01 and 11.02, American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

4 *Standard Methods for the Examination of Water and Wastewater*, 18th Edition, 1992, American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005.

5 Available from Books and Open-File Reports Section, U.S. Geological Survey, Federal Center, Box 25425, Denver, CO 80225-0425.

6 "Methods for the Determination of Inorganic Substances in Environmental Samples," EPA-600/R-93-100, August 1993. Available at NTIS, PB94-121811.

7 Technical Bulletin 601 "Standard Method of Test for Nitrate in Drinking Water," July 1994, PN 221890-001, ATI Orion, 529 Main Street, Boston, MA 02129. This method is identical to Orion WeWWG/5880, which is approved for nitrate analysis. ATI Orion republished the method in 1994, and renumbered it as 601, because the 1985 manual "Orion Guide to Water and Wastewater Analysis," which contained WeWWG/5880, is no longer available.

8 Method B-1011, "Waters Test Method for Determination of Nitrite/Nitrate in Water Using Single Column Ion Chromatography," Millipore Corporation, Waters Chromatography Division, 34 Maple Street, Milford, MA 01757.

9 Method 100.1, "Analytical Method for Determination of Asbestos Fibers in Water," EPA-600/4-83-043, EPA, September 1983. Available at NTIS, PB 83-260471.

10 Method 100.2, "Determination of Asbestos Structure Over 10-µm In Length in Drinking Water," EPA-600/R-94-134, June 1994. Available at NTIS, PB 94-201902.

11 Industrial Method No. 129-71W, "Fluoride in Water and Wastewater," December 1972, and Method No. 380-75WE, "Fluoride in Water and Wastewater," February 1976, Technicon Industrial Systems, Tarrytown, NY 10591.

12 GLI Method 2, "Turbidity," November 2, 1992, Great Lakes Instruments, Inc., 8855 North 55th Street, Milwaukee, Wisconsin 53223

Table IV-3 Approved Methods for Primary Organic Chemicals [§141.24(e)]

Contaminant	Method[3]
Benzene	502.2, 524.2
Carbon tetrachloride	502.2, 524.2, 551
Chlorobenzene	502.2, 524.2
1,2-Dichlorobenzene	502.2, 524.2
1,4-Dichlorobenzene	502.2, 524.2
1,2-Dichloroethane	502.2, 524.2
cis-1,2-Dichloroethylene	502.2, 524.2
trans-1,2-Dichloroethylene	502.2, 524.2
Dichloromethane	502.2, 524.2
1,2-Dichloropropane	502.2, 524.2
Ethylbenzene	502.2, 524.2
Styrene	502.2, 524.2
Tetrachloroethylene	502.2, 524.2, 551
1,1,1-Trichloroethane	502.2, 524.2, 551
Trichloroethylene	502.2, 524.2, 551
Toluene	502.2, 524.2
1,2,4-Trichlorobenzene	502.2, 524.2
1,1-Dichloroethylene	502.2, 524.2
1,1,2-Trichloroethane	502.2, 524.2
Vinyl chloride	502.2, 524.2
Xylenes (total)	502.2, 524.2
2,3,7,8-TCDD (dioxin)	1613
2,4-D	515.2, 515.1, 555
Alachlor	505[1], 507, 508.1, 525.2
Atrazine	505[1], 507, 508.1, 525.2
Benzo(a)pyrene	525.2, 550, 550.1
Carbofuran	531.1, 6610

Contaminant	Method[3]
Chlordane	505, 508, 508.1, 525.2
Dalapon	515.1, 552.1
Di(2-ethylhexyl)adipate	506, 525.2
Di(2-ethylhexyl)phthalate	506, 525.2
Dibromochloropropane (DBCP)	504.1, 551
Dinoseb	515.2,515.1, 555
Diquat	549.1
Endothall	548.1
Endrin	505, 508, 508.1, 525.2
Ethylene dibromide (EDB)	504.1, 551
Glyphosate	547, 6651
Heptachlor	505, 508, 508.1, 525.2
Heptachlor Epoxide	505, 508, 508.1, 525.2
Hexachlorobenzene	505, 508, 508.l, 525.2
Hexachlorocyclopentadiene	505, 508, 508.1, 525.2
Lindane	505, 508, 508.1, 525.2
Methoxychlor	505, 508, 508.1, 525.2
Oxamyl	531.1, 6610
PCBs (as decachlorobiphenyl)[2] (as Aroclors)	508A 505, 508
Pentachlorophenol	515.1, 515.2, 525.2, 555
Picloram	515.1, 515.2, 555
Simazine	505[1], 507, 508.1, 525.2
2,4,5-TP (Silvex)	515.1, 515.2, 555
Toxaphene	505, 508, 525.2
Total Trihalomethanes	502.2, 524.2, 551

[1] A nitrogen-phosphorous detector should be substituted for the electron capture detector in Method 505 (or another approved method should be used) to determine alachlor, atrazine and simazine, if lower detection limits are required.

[2] PCBs are qualitatively identified as Aroclors and measured for compliance purposes as decachlorobiphenyl

using Method 508A.

[3] Methods 502.2, 505, 507, 508, 508A, 515.1 and 531.1 are in Methods for the Determination of Organic Compounds in Drinking Water, EPA-600/4-88-039, December 1988, Revised, July 1991. Methods 506, 547, 550, 550.1 and 551 are in Methods for the Determination of Organic Compounds in Drinking Water - Supplement I, EPA-600-4-90-020, July 1990. Methods 515.2, 524.2, 548.1, 549.1, 552.1 and 555 are in Methods for the Determination of Organic Compounds in Drinking Water - Supplement II, EPA-600/R-92-129, August 1992. Method 1613, Tetra-Through Octa- Chlorinated Dioxins and Furans by Isotopic Dilution HRGC/HRMS, EPA-81/B-94-003, October 1994 These documents are available from the National Technical Information Service, NTIS PB91-231480, PB91-146027 and PB92-207703 and PB95-104774, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll-free number is 800-553-6847. Method 1613 is available from USEPA Office of Water Resource Center (RC-4100), 401 M. Street S.W., Washington, D.C. 20460. The phone number is 202-260-7786. EPA Methods 504.1, 508.1 and 525.2 are available from US EPA NERL, Cincinnati, OH 45268. The phone number is (513)-569-7586. Method 6651 is contained in the 18th edition of *Standard Methods for the Examination of Water and Wastewater*, 1992, and Method 6610 is contained in the *Supplement to the 18th edition of Standard Methods for the Examination of Water and Wastewater*, 1994, American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005.

Table IV-4 Approved Methods for "Unregulated" Contaminants (§141.40)

Regulations specified in §141.40 require monitoring for certain contaminants to which maximum contaminant levels do not apply. These chemicals are called "unregulated" contaminants, and presently include sulfate, 34 volatile organic chemicals (VOCs) and 13 synthetic organic chemicals (SOCs).

Analysis for the 34 unregulated VOCs listed under paragraphs (e) and (j) of §141.40 shall be conducted using the following recommended methods, or their equivalent as determined by EPA.

"Unregulated" VOC Contaminants	Method
Chloroform	502.2, 524.2, 551
Bromodichloromethane	502.2, 524.2, 551
Bromoform	502.2, 524.2, 551
Chlorodibromomethane	502.2, 524.2, 551
Bromobenzene	502.2, 524.2
Bromomethane	502.2, 524.2
Chloroethane	502.2, 524.2
Chloromethane	502.2, 524.2
o-Chlorotoluene	502.2, 524.2
p-Chlorotoluene	502.2, 524.2
Dibromomethane	502.2, 524.2
m-Dichlorobenzene	502.2, 524.2
1,1-Dichloroethane	502.2, 524.2
1,3-Dichloropropane	502.2, 524.2
2,2-Dichloropropane	502.2, 524.2
1,1-Dichloropropene	502.2, 524.2
1,3-Dichloropropene	502.2, 524.2
1,1,2,2-Tetrachloroethane	502.2, 524.2
1,1,1,2-Tetrachloroethane	502.2, 524.2
1,2,3-Trichloropropane	502.2, 524.2, 504.1

State Discretionary Contaminants	METHODS
Bromochloromethane	502.2, 524.2
n-Butylbenzene	502.2, 524.2

State Discretionary Contaminants	METHODS
sec-Butylbenzene	502.2, 524.2
tert-Butylbenzene	502.2, 524.2
Dichlorodifluoromethane	502.2, 524.2
Fluorotrichloromethane	502.2, 524.2
Hexachlorobutadiene	502.2, 524.2
Isopropylbenzene	502.2, 524.2
p-Isopropyltoluene	502.2, 524.2
Naphthalene	502.2, 524.2
n-Propylbenzene	502.2, 524.2
1,2,3-Trichlorobenzene	502.2, 524.2
1,2,4-Trimethylbenzene	502.2, 524.2
1,3,5-Trimethylbenzene	502.2, 524.2

Analysis for the 13 unregulated SOCs listed under paragraph (n)(11) of §141.40 shall be conducted using the following recommended methods.

"Unregulated" SOC Contaminants	Methods
Aldicarb	531.1, 6610*
Aldicarb sulfone	531.1, 6610*
Aldicarb sulfoxide	531.1, 6610*
Aldrin	505, 508, 525.2, 508.l
Butachlor	507, 525.2
Carbaryl	531.1, 6610*
Dicamba	515.1, 515.2, 555
Dieldrin	505, 508, 525.2, 508.1
3-Hydroxycarbofuran	531.1, 6610*
Methomyl	531.1, 6610*
Metolachlor	507, 525.2, 508.1
Metribuzin	507, 525.2, 508.1
Propachlor	508, 525.2, 508.1

Analysis for the unregulated inorganic contaminant listed under paragraph (n)(12) of §141.40 shall be conducted using the following recommended methods.

"Unregulated" Inorganic Contaminants	**Methods EPA**	**ASTM**	**SM**
Nickel	200.7		3120B
	200.8		
	200.9		
			3111B
			3113B
Sulfate	300.0	D4327-91	4110B
	375.2		4500-SO_4-F
			4500-SO_4-C,D

*A Standard Methods method.

Sources for the Standard Methods and ASTM sulfate methods are referenced above under methods for inorganic chemicals. The EPA methods are contained in "Methods for the Determination of Inorganic Substances in Environmental Samples," EPA-600/R-93-100, August 1993, which is available at NTIS, PB94-121811.

Table IV-5 Approved Methods for Disinfectant Residuals

Public water systems must measure residual disinfectant concentrations with one of the analytical methods in the following table. The methods are contained in the 18th edition of *Standard Methods for the Examination of Water and Wastewater*.

Residual[1]	**Methodology**	**SM**[3]
Free Chlorine[2]	Amperometric Titration DPD Ferrous Titrimetric DPD Colorimetric Syringaldahyde (FACTS)	4500-Cl D 4500-Cl F 4500-Cl G 4500-Cl H
Total Chlorine[2]	Amperometric Titration Amperometric Titration (low level measurement) DPD Ferrous Titrimetric DPD Colorimetric Iodometric Electrode	4500-Cl D 4500-Cl E 4500-Cl F 4500-Cl G 4500-Cl I
Chlorine Dioxide	Amperometric Titration DPD Method Amperometric Titration	4500-ClO_2 C 4500-ClO_2 D 4500-ClO_2 E
Ozone	Indigo Method	4500-O_3 B

Footnotes

[1] If approved by the State, residual disinfectant concentrations for free chlorine and combined chlorine also may be measured by using DPD colorimetric test kits.
[2] Free and total chlorine residuals may be measured continuously by adapting a specified chlorine residual method for use with a continuous monitoring instrument provided the chemistry, accuracy, and precision of the measurement remain the same. Instruments used for continuous monitoring must be calibrated with a grab sample measurement at least every five days, or with protocol approved by the State.
[3] *Standard Methods for the Examination of Water and Wastewater*, 18th Edition, 1992

Table IV-6 Recommended Methods for Secondary Drinking Water Contaminants

Analyses of aluminum, chloride, color, copper, fluoride, foaming agents, iron, manganese, odor, silver, sulfate, total dissolved solids (TDS) and zinc to determine compliance under §143.3 may be conducted with the methods in the following Table. Criteria for analyzing aluminum, copper, iron, manganese, silver, and zinc samples with digestion or directly without digestion, and other mandatory procedures are contained in the Technical Notes in Section IV of this document. Measurement of pH may be conducted with one of the methods listed above in Section I under "Methods for Inorganic Chemicals."

Contaminant	EPA	ASTM[1]	SM[2]	Other
Aluminum	200.7[3]		3120B	
	200.8[3]		3113B	
	200.9[3]		3111D	
Chloride	300.0[4]	D4327-91	4110B	
			4500-Cl^--D	
Color			2120B	
Foaming Agents			5540C	
Iron	200.7[3]		3120B	
	200.9[3]		3111B	
			3113B	
Manganese	200.7[3]		3120B	
	200.8[3]		3111B	
	200.9[3]		3113B	
Odor			2150B	
Silver	200.7[3]		3120B	I-3720-85[6]
	200.8[3]		3111B	
	200.9[3]		3113B	
Sulfate	300.0[4]	D4327-91	4110B	
	375.2[4]		4500-SO_4-F	
			4500-SO_4-C,D	
TDS			2540C	
Zinc	200.7[3]		3120B	
	200.8[3]		3111B	

Footnotes

[1] *Annual Book of ASTM Standards*, Vols. 11.01 and 11.02, American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.
[2] *Standard Methods for the Examination of Water and Wastewater*, 18th Edition, 1992, American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005.
[3] "Methods for the Determination of Metals in Environmental Samples - Supplement I," EPA-600/R-94-111, May 1994. Available at NTIS, PB94-184942.
[4] "Methods for the Determination of Inorganic Substances in Environmental Samples," EPA-600/R-93-100, August 1993. Available at NTIS, PB94-121811.
[5] Industrial Method No. 129-71W, "Fluoride in Water and Wastewater," December 1972, and Method No. 380-75WE, "Fluoride in Water and Wastewater," February 1976, Technicon Industrial Systems, Tarrytown, NY 10591.
[6] Available from Books and Open-File Reports Section, U.S. Geological Survey, Federal Center, Box 25425, Denver, CO 80225-0425.

Table IV-7 Preservation and Holding Times for Regulated Parameters

Parameter/ Method	Preservative	Sample Holding Time	Extract Holding Time	Suggested Sample Size	Type of Container
Metals (except Hg)	HNO_3 pH<2	6 months		1 L	Plastic or Glass
Mercury	HNO_3 pH<2	28 days		100 mL	Plastic or Glass
Alkalinity	Cool, 4C	14 days		100 mL	Plastic or Glass
Asbestos	Cool, 4C	48 hours			Plastic or Glass
Chloride	none	28 days		50 mL	Plastic or Glass
Residual Disinfectant	none	immediately		200 mL	Plastic or Glass
Color	Cool, 4C	48 hours		50 mL	Plastic or Glass
Conductivity	Cool, 4C	28 days		100 mL	Plastic or Glass
Cyanide	Cool, 4C, Ascorbic acid (if chlorinated), NaOH pH>12	14 days		1 L	Plastic or Glass
Fluoride	none	28 days		300 mL	Plastic or Glass
Foaming Agents	Cool, 4C	48 hours			
Nitrate (chlorinated)	Cool, 4C	28 days		100 mL	Plastic or Glass
Nitrate (non chlorinated)	Cool, 4C, H_2SO_4, pH<2	14 days		100 mL	Plastic or Glass
Nitrite	Cool, 4C	48 hours		50 mL	Plastic or Glass
Odor	Cool, 4C	24 hours		200 mL	Glass
pH	none	immediately		25 mL	Plastic or Glass
o-Phosphate	Filter immediately, Cool, 4C	48 hours		50 mL	Plastic or Glass
Silica	Cool, 4C	28 days		100 mL	Plastic
Solids (TDS)	Cool, 4C	7 days		100 mL	Plastic or Glass

Parameter/ Method	Preservative	Sample Holding Time	Extract Holding Time	Suggested Sample Size	Type of Container
Sulfate	Cool, 4C	28 days		50 mL	Plastic or Glass
Temperature	none	immediately		1 L	Plastic or Glass
Turbidity	Cool, 4C	48 hours		100 mL	Plastic or Glass
502.2	Sodium Thiosulfate or Ascorbic Acid, 4C, HCl pH<2	14 days		40-120 mL	Glass with Teflon Lined Septum
504.1	Sodium Thiosulfate Cool, 4C,	14 days	4C, 24 hours	40 mL	Glass with Teflon Lined Septum
505	Sodium Thiosulfate Cool, 4C	14 days (7 days for Heptachlor)	4C, 24 hours	40 mL	Glass with Teflon Lined Septum
506	Sodium Thiosulfate Cool, 4C, Dark	14 days	4C, dark 14 days	1 L	Amber Glass with Teflon lined Cap
507	Sodium Thiosulfate Cool, 4C, Dark	14 days(see method for exceptions)	4C, dark 14 days	1 L	Amber Glass with Teflon Lined Cap
508	Sodium Thiosulfate Cool, 4C, Dark	7 days (see method for exceptions)	4C, dark 14 days	1 L	Glass with Teflon Lined Cap
508A	Cool, 4C	14 days	30 days	1 L	Glass with Teflon Lined Cap
508.1	Sodium Sulfite HCl pH<2 Cool, 4C	14 days (see method for exceptions)	30 days	1 L	Glass with Teflon Lined Cap
515.1	Sodium Thiosulfate Cool, 4C, Dark	14 days	4C, dark 28 days	1 L	Amber Glass with Teflon Lined Cap
515.2	Sodium Thiosulfate HCl pH<2 Cool, 4C, Dark	14 days	≤4C, dark 14 days	1 L	Amber Glass with Teflon Lined Cap

Parameter/ Method	Preservative	Sample Holding Time	Extract Holding Time	Suggested Sample Size	Type of Container
524.2	Ascorbic Acid HCl pH<2, Cool 4C	14 days		40-120 mL	Glass with Teflon Lined Septum
525.2	Sodium Sulfite, Dark, Cool, 4C, HCl pH<2	14 days (see method for exceptions)	30 days from collection	1 L	Amber Glass with Teflon Lined Cap
531.1, 6610	Sodium Thiosulfate, Monochloroacetic acid, pH<3, Cool, 4C	Cool 4C 28 days		60 mL	Glass with Teflon Lined Septum
547	Sodium Thiosulfate Cool, 4C	14 days(18 mo.frozen)		60 mL	Glass with Teflon Lined Septum
548.1	Sodium Thiosulfate (HCl pH 1.5-2 if high biological activity) Cool, 4C, Dark	7 days	14 days ≤4C	≥ 250 mL	Amber Glass with Teflon Lined Septum
549.1	Sodium Thiosulfate, (H_2SO_4 pH<2 if biologically active) Cool, 4C, Dark	7 days	21 days	≥ 250mL	High Density Amber Plastic or Silanized Amber Glass
550, 550.1	Sodium Thiosulfate Cool, 4C, HCl pH<2	7 days	550, 30 days 550.1, 40 days Dark, 4C	1 L	Amber Glass with Teflon Lined Cap
551	Sodium Thiosulfate, Sodium Sulfite, Ammonium Chloride, or Ascorbic Acid, HCL pH 4.5-5.0 Cool, 4C	14 days		≥ 40 mL	Glass with Teflon Lined Septum
555	Sodium Sulfite HCl, pH≤2 Dark, Cool 4C	14 days		≥ 100 mL	Glass with Teflon lined cap

Parameter/ Method	Preservative	Sample Holding Time	Extract Holding Time	Suggested Sample Size	Type of Container
1613B	Sodium Thiosulfate Cool, 0-4C, Dark		Recommend 40 days	1 L	Amber Glass with Teflon Lined Cap

Table IV-8 Detection Limit Requirements in the CFR (mg/l)

Inorganics	MCL*	MCLG	Detection Limit Required to Composite [§141.23(a)(4)]
Asbestos	7 MFL	7 MFL	1.4 MFL
Cyanide	0.2	0.2	0.04
Fluoride	4.0		0.8
Nitrate	10	10	2
Nitrite	1	1	0.2

* The monitoring trigger for the inorganics is the MCL except for both nitrate and nitrite, which are 1/2 the MCL

Metals	MCL *	MCLG	Detection Limit Required to Composite [§141.23(a)(4)]
Antimony	0.006	0.006	0.001
Arsenic	0.05	-	0.01
Barium	2	2	0.4
Beryllium	0.004	0.004	0.0008
Cadmium	0.005	0.005	0.001
Chromium	0.1	0.1	0.02
Copper**	1.3	1.3	0.001 0.02 (for direct aspiration AA)
Lead**	0.015	zero	0.001
Mercury	0.002	0.002	0.0004
Selenium	0.05	0.05	0.01
Thallium	0.002	0.0005	0.0004

* The monitoring trigger for metals is the MCL unless compositing, then 1/5 MCL is required

**Action Level

TABLE IV-8 Detection Limit Requirements in the CFR (mg/L)

Volatile Organics*	MCL	MCLG	Required MDL
THMs	0.10	NA	NA
Benzene	0.005	zero	0.0005
Carbon tetrachloride	0.005	zero	0.0005
Chlorobenzene	0.1	0.1	0.0005
o-Dichlorobenzene	0.6	0.6	0.0005
p-Dichlorobenzene	0.075	0.075	0.0005
1.2-Dichloroethane	0.005	zero	0.0005
1,1-Dichloroethylene	0.007	0.007	0.0005
c-1,2-Dichloroethylene	0.07	0.07	0.0005
t-1,2-Dichloroethylene	0.1	0.1	0.0005
Dichloromethane	0.005	zero	0.0005
1,2-Dichloropropane	0.005	zero	0.0005
Ethylbenzene	0.7	0.7	0.0005
Styrene	0.1	0.1	0.0005
Tetrachloroethylene	0.005	zero	0.0005
Toluene	1	1	0.0005
1,2,4-Trichlorobenzene	0.07	0.07	0.0005
1,1,1-Trichloroethane	0.2	0.2	0.0005
1,1,2-Trichloroethane	0.005	0.003	0.0005
Trichloroethylene	0.005	zero	0.0005
Vinyl chloride	0.002	zero	0.0004
Xylenes	10	10	0.0005

* A laboratory must be able to achieve an MDL of 0.5 μg/L to be certified to analyze samples for compliance monitoring [§141.24(f)(17)(i)(E) and (ii)(C)]. This is also the monitoring trigger for VOCs [§141.24(f)(11)].

TABLE IV-8 Detection Limit Requirements in the CFR (mg/l)

SOCs	MCL	MCLG	Monitoring Trigger*
Alachlor	0.002	zero	0.0002
Atrazine	0.003	0.003	0.0001
Benzo(a)pyrene	0.0002	zero	0.00002
Carbofuran	0.04	0.04	0.0009
Chlordane	0.002	zero	0.0002
2,4-D	0.07	0.07	0.0001
Di(2-ethylhexyl)adipate	0.4	0.4	0.0006
Di(2-ethylhexyl)phthalate	0.006	zero	0.0006
Dibromochloropropane (DBCP)	0.0002	zero	0.00002
Dalapon	0.2	0.2	0.001
Dinoseb	0.007	0.007	0.0002
Dioxin (2,3,7,8-TCDD)	$3x10^{-8}$	zero	$5x10^{-9}$
Diquat	0.02	0.02	0.0004
Endothall	0.1	0.1	0.009
Endrin	0.002	0.002	0.00001
Ethylenedibromide (EDB)	0.00005	zero	0.00001
Glyphosate	0.7	0.7	0.006
Heptachlor	0.0004	zero	0.00004
Heptachlor Epoxide	0.0002	zero	0.00002
Hexachlorobenzene	0.001	zero	0.0001
Hexachlorocyclopentadiene	0.05	0.05	0.0001
Lindane	0.0002	0.0002	0.00002
Methoxychlor	0.04	0.04	0.0001
Oxamyl	0.2	0.2	0.002
PCBs (as decachlorobiphenyl)	0.0005	zero	0.0001
Pentachlorophenol	0.001	zero	0.00004
Picloram	0.5	0.5	0.0001
Simazine	0.004	0.004	0.00007
Toxaphene	0.003	zero	0.001
2,4,5-TP (Silvex)	0.05	0.05	0.0002

*The monitoring triggers for SOCs listed in the regulation are also required for compositing but

are not required by regulation for certification [§141.24(g)(7), (10)(i) and (18)].

Table IV-9 Performance Evaluation Sample Acceptance Criteria in the CFR Primary and Secondary Drinking Water Regulations [§141.23(k)(3)(ii) and 141.24(f)(17) and (19)]

Regulated Parameter	MCL/ [SMCL] mg/L	MCLG mg/L	Acceptance Limit
METALS			
Aluminum	[0.05-0.2]	-	
Antimony	0.006	0.006	± 30%
Arsenic	0.05	-	
Barium	2	2	± 15%
Beryllium	0.004	0.004	± 15%
Cadmium	0.005	0.005	± 20%
Calcium	-	-	
Chromium	0.1	0.1	± 15%
Copper	1.3/90% [1.0]	1.3	± 10%
Iron	[0.3]	-	
Lead	0.015/90%	zero	± 30%
Manganese	[0.05]	-	
Mercury	0.002	0.002	± 30%
Selenium	0.05	0.05	± 20%
Silica	-	-	
Silver	[0.1]		
Sodium	20[1]	-	
Thallium	0.002	0.0005	± 30%

[1] Recommended Level

Regulated Parameter	MCL/ [SMCL] mg/L	MCLG mg/L	Acceptance Limit
Zinc	[5.0]	-	

Regulated Parameter	MCL/ [SMCL] mg/L	MCLG mg/L	Acceptance Limit
INORGANICS			
Alkalinity	-	-	
Asbestos	7MF/L>10u	7MF/L>10u	2 Std Dev
Chloride	[250]	-	
Residual Disinfectant	detectable	-	
Color	[15cu]	-	
Conductivity	-	-	
Corrosivity	[non-corrosive]	-	
Cyanide	0.2	0.2	$\pm$ 25%
Fluoride	4.0 [2.0]	-	$\pm$ 10%
Foaming Agents	[0.5]	-	
Nitrate (as N)	10	10	$\pm$ 10%
Nitrite (as N)	1	1	$\pm$ 15%
Nitrate/Nitrite (as N)	10	10	
Odor	[3ton]	-	
pH	6.5-8.5 [6.5-8.5]	-	
o-Phosphate	-	-	
Solids(TDS)	[500]	-	
Sulfate	deferred [250]	deferred	
Temperature	-	-	

Regulated Parameter	MCL/ [SMCL] mg/L	MCLG mg/L	Acceptance Limit
VOLATILES			
Trihalomethanes(Total)	0.10		± 20%
Benzene	0.005	zero	*
Carbon tetrachloride	0.005	zero	*
Chlorobenzene	0.1	0.1	*
p-Dichlorobenzene	0.075 [0.005]	0.075	*
o-Dichlorobenzene	0.6	0.6	*
1,2-Dichloroethane	0.005	zero	*
1,1-Dichloroethylene	0.007	0.007	*
c-1,2-Dichloroethylene	0.07	0.07	*
t-1,2-Dichloroethylene	0.1	0.1	*
Dichloromethane	0.005	zero	*
1,2-Dichloropropane	0.005	zero	*
Ethylbenzene	0.7	0.7	*
Styrene	0.1	0.1	*
Tetrachloroethylene	0.005	zero	*
Toluene	1	1	*
1,2,4-Trichlorobenzene	0.07	0.07	*
1,1,1-Trichloroethane	0.2	0.2	*
1,1,2-Trichloroethane	0.005	0.003	*
Trichloroethylene	0.005	zero	*
Vinyl chloride	0.002	zero	± 40%
Xylenes(Total)	10	10	*

Regulated Parameter	MCL/ [SMCL] mg/L	MCLG mg/L	Acceptance Limit
SYNTHETIC ORGANICS			
Alachlor	0.002	zero	± 45%
Aldicarb	Postponed	Postponed	2 Std Dev
Aldicarb Sulfoxide	Postponed	Postponed	2 Std Dev
Aldicarb Sulfone	Postponed	Postponed	2 Std Dev
Atrazine	0.003	0.003	± 45%
Carbofuran	0.04	0.04	± 45%
Chlordane	0.002	zero	± 45%
2,4-D	0.07	0.07	± 50%
Dalapon	0.2	0.2	2 Std Dev
Dibromochloropropane(DBCP)	0.0002	zero	± 40%
Dinoseb	0.007	0.007	2 Std Dev
Diquat	0.02	0.02	2 Std Dev
Endothall	0.1	0.1	2 Std Dev
Endrin	0.002	0.002	± 30%
Ethylenedibromide(EDB)	0.00005	zero	± 40%
Glyphosate	0.7	0.7	2 Std Dev
Heptachlor	0.0004	zero	± 45%
Heptachlor epoxide	0.0002	zero	± 45%
Lindane	0.0002	0.0002	± 45%
Methoxychlor	0.04	0.04	± 45%
Oxamyl (Vydate)	0.2	0.2	2 Std Dev
Pentachlorophenol	0.001	zero	± 50%

Regulated Parameter	MCL/ [SMCL] mg/L	MCLG mg/L	Acceptance Limit
Picloram	0.5	0.5	2 Std Dev
Simazine	0.004	0.004	2 Std Dev
Toxaphene	0.003	zero	± 45%
2,4,5-TP(Silvex)	0.05	0.05	± 50%
Hexachlorobenzene	0.001	zero	2 Std Dev
Hexachlorocyclopentadiene	0.05	0.05	2 Std Dev
Benzo(a)pyrene	0.0002	zero	2 Std Dev
PCBs (as decachlorobiphenyl)	0.0005	zero	0-200%
2,3,7,8-TCDD(Dioxin)	$3x10^{-8}$	zero	2 Std Dev
Acrylamide	Treatment	zero	NA
Epichlorohydrin	Treatment	zero	NA
Di(2-ethylhexyl)adipate	0.4	0.4	2 Std Dev
Di(2-ethylhexyl)phthalate	0.006	zero	2 Std Dev

* the acceptance limits for VOCs are ±20% at ≥0.010mg/L and ±40% at <0.010mg/L
NA - Not Applicable

Sample Checklists for On-Site Evaluation of Laboratories Involved in Analysis of Public Water Supplies

CHEMISTRY

Laboratory	
Street	
City, State	
Zip	
Telephone No. Fax No.	
Audit Team Leader	
Audit Team Members	
Audit Team Affiliation	
Date	

Laboratory _____ **Evaluator** _____

Location _____ **Date** _____

PHYSICAL FACILITY

Item	Acceptable Yes	Acceptable No	Comments
Environment			
Heating/Cooling/Humidity			
Lighting			
Ventilation/Exhaust hoods			
Cleanliness			
Electrical and water services			
Work Space			
Separation of incompatible testing areas			
Controlled access where appropriate			
Housekeeping			
Unencumbered access			
Adequate work space			
Storage			
Chemicals properly stored and dated			
Standards properly stored, dated and labeled with concentration, preparer's name and solvent, origin, purity & traceability			
Computers & automated equipment			
Safety procedures			

Laboratory _____ **Evaluator** _____

Location _____ **Date** _____

PERSONNEL (Use additional paper if necessary.)

Position/ Title	**Name**	**Education Level Degree/Major***	**Specialized Training**	**Present Specialty**	**Experience**
Laboratory Director					
Manager					
Supervisors					
Instrument Operators					
AA					
TEM					
HPLC					
GC					
ICP					
GC/MS					
IC					
Other analysts					

	Yes No	Comments
An organization chart available		
QA manager has line authority		
Personnel job descriptions and resumes available		
Personnel training documented		

*If the major is not in chemistry, list hours of college level courses in chemistry.

Laboratory _____ **Evaluator** _____

Location _____ **Date** _____

QUALITY ASSURANCE AND DATA REPORTING

Item	Comments	Satisfactory Yes	No
QA plan			
Organization			
Sampling SOPs available and used Preservation Containers Holding times Samplers trained			
Sample Rejection			
Laboratory sample handling Log in procedure Bound log book or secure computer log in Storage Tracking			
Analytical Methods Written methods available Approved methods used SOPs available and used			
Calibration Type and frequency Source of standards Data comparability Instrument tuning			
Blanks Trip Field Method			
Method Detection Limits Initial Frequency Acceptability			
Precision and Accuracy Initial Frequency Acceptability Control charts Laboratory fortified blanks Matrix duplicates			

Item	Comments	Satisfactory Yes	Satisfactory No
Other QC Checks Performance check samples Internal and surrogate standards Matrix spikes and replicates			
Qualitative Identification/ Confirmation			
Performance Evaluation Samples Analyzed			
Data Reduction and Validation Calculations Transcription Significant Figures Validation			
Preventive Maintenance			
Records Retention			
Corrective Action			

Laboratory _____ **Evaluator** _____

Location _____ **Date** _____

Item	No. of Units	Method	Manufacturer	Model	Satisfactory Yes	Satisfactory No
Analytical Balance 0.1 mg readability Stable base ASTM type 1 or 2 weights (formerly Class S) Service contracts						
Magnetic Stirrer Variable speed, TFE coated stir bar						
pH Meter Accuracy ±0.1 units Line or battery Usable with specific ion electrodes						
Conductivity Meter Readable in ohms or mhos Range of 2 ohms to 2 mhos Line or battery						
Hot Plate - temp control						
Centrifuge To 3000 rpm, Option of 4 x 50 mL						
Color Standards To verify wavelengths photometers Should cover 200-800 nm						

Item	No. of Units	Method	Manufacturer	Model	Satisfactory Yes	Satisfactory No
Refrigerator/Freezer Standard laboratory, explosion proof for organics Capable of maintaining nominal temperature of 4C						
Drying Oven Gravity or convection Controlled from room temp to 180°C or higher(±2°C)						
Muffle Furnace To 450°C for cleaning organic glassware						
Thermometer Mercury filled Celsius 1°C or finer subdivision to 180°C NBS Certified or traceable						
Glassware Borosilicate Volumetrics should be Class A						
Spectrophotometer Range 400 - 700 nm Band width - < 20 nm Use several size & shape cells Path length 1 - 5 cm		Cyanide, Fluoride Disinfectants Mercury Nitrate/Nitrite o-Phosphate Sulfate , Silica				
Filter Photometer Range 400 - 700 nm Band width 10 -70 nm Use several size & shape cells Pathlength 1 - 5 cm		same as above				

Item	No. of Units	Method	Manufacturer	Model	Satisfactory Yes	No
Amperometric Titrator		Disinfectants				
Specific Ion Meter Accuracy ± 1 mV		Cyanide Fluoride Nitrate				
Inductively Coupled Plasma (sequential,simultaneous) Computer controlled Background correction Radio frequency generator Argon gas supply Mass Spectrometer Range 5-250 amu Resolution 1 amu peak width at 5% peak height		200.7, 3120B 200.8				
Water Bath Electric or steam heat Controllable within 5°C to 100°C		Mercury Nitrate Pesticides				
Ion Chromatograph Conductivity detector, UV detector Suppressor column, Separator column		Fluoride , Chloride Nitrate/Nitrite o-Phosphate Sulfate				

Item	No. of Units	Method	Manufacturer	Model	Satisfactory Yes	Satisfactory No
Atomic Absorption Spectrophotometer Single channel, Single or double beam Grating monochrometer Photo multiplier detector Adjustable slits, Range 190-800 nm Readout system: Response time compatible with AA Able to detect positive interference for furnace Chart recorder, CRT or hard copy printer		Metals				
Air/Acetylene commercial grade		Barium, Calcium Nickel, Sodium Copper				
Nitrous Oxide - comm. grade		Barium				
Graphite Furnace Argon or Nitrogen (commercial grade) Reach required temperatures Background corrector provision for offline analysis Pipets and tips microliter capacity with disposable tips 5-100 microliters metal free tips		Antimony, Lead Arsenic, Barium Beryllium Cadmium, Nickel Chromium Selenium Thallium Copper				
Arsine Generator		Arsenic, Selenium				
Hydride Generator hydrogen, commercial grade		Antimony Arsenic, Selenium				

Item	No. of Units	Method	Manufacturer	Model	Satisfactory Yes	Satisfactory No
Mercury Analyzer Spectrophotometer Dedicated analyzer having a mercury lamp acceptable Adsorption cell: 10 cm quartz cell with quartz end windows or 11.5 cm plexiglass cell with 2.5 cm ID Air pump to deliver flow of at least 1 L/min Aeration tube with coarse glass frit Flowmeter to measure air flow of 1 L/min Drying unit: 6 in. tube with 20 grams magnesium perchlorate or heating device or lamp to prevent condensation on cell		Mercury				
Glassware Separatory funnels Kuderna Danish (K-D) concentrators		SOCs				
Gas Chromatograph Split/splitless injection Oven temp. control ± 0.2°C Recorder, hard copy Oven temp. programmer Sub-ambient accessory Variable-constant differential flow control		Organics				
Electron Capture detector Linearized		504.1, 505 508, 508.1 508A, 515.1 515.2, 551, 552.1				

Item	No. of Units	Method	Manufacturer	Model	Satisfactory Yes	No
Electrolytic Conductivity/Photoionization detector		502.2 506 (PID only)				
Nitrogen Phosphorus detector		507				
Mass spectrometer (quadrupole or ion trap) All glass enrichment device All glass transfer line Electron ionization at ≥70 eV Scanning 35-260 amu ≤2 sec Interfaced data system		524.2, 525.2 548.1				
Purge & Trap system All glass purger 5/25 mL sample size		502.2, 524.2				

Item	No. of Units	Method	Manufacturer	Model	Satisfactory Yes	Satisfactory No
High Performance Liquid Chromatograph Constant flow Capable of injecting 20-500 μL						
Gradient system post-column reactor fluorescence detector excitation at 330 nm (230?) detection at >418 nm		531.1, 6610				
Gradient system UV detector at 254 nm fluorescence detector excitation at 280 nm detection at > 389 nm		550, 550.1				
Isocratic system photodiode array detector excitation at 257 nm detection at >308 nm		549.1				
Isocratic system post-column reactor fluorescence detector excitation at 340 nm detection at >455 nm		547				
Gradient system photodiode array/UV detector 210-310 nm		555				

Item	No. of Units	Method	Manufacturer	Model	Satisfactory Yes	Satisfactory No
Auto Analysis System multi-channel pump manifold, colorimeter		Cyanide, Silica Fluoride Nitrate/nitrite o-Phosphate Sulfate				
Transmission Electron Microscope 80 kV 300-100,000X magnification 1 nm resolution calibrate screen SAED and ED		Asbestos				

Laboratory _____ **Evaluator** _____

Location _____ **Date** _____

METHODOLOGY

Contaminant	**Method(s)** Name/Number and revision	**Reference** Cite source, year, page	**Samples/Mo**	**Satisfactory** **Yes**	**No**
Antimony					
Arsenic					
Barium					
Beryllium					
Cadmium					
Chromium					
Copper					
Lead					
Mercury					
Selenium					
Thallium					
Alkalinity					
Calcium					
o-Phosphate					
Silica					
Temperature					

Contaminant	**Method(s)** Name/Number and revision	**Reference** Cite source, year, page	**Samples/Mo**	**Satisfactory** **Yes**	**No**
Asbestos					
Cyanide					
Fluoride					
Nitrate					
Nitrite					
Total THMs					
VOCs					
Herbicides					
Pesticides					
EDB/DBCP					
Dioxin					
Other SOCs					
PCBs					
Carbamates					
Diquat					
Endothall					
Glyphosate					
Chlorine					
Chlorine dioxide					

Contaminant Ozone	**Method(s)** Name/Number and revision	**Reference** Cite source, year, page	**Samples/Mo**	**Satisfactory** **Yes**	**No**
Unregulated VOCs					
Unregulated Pesticides					
Unregulated Herbicides					
Unregulated Carbamates					
Aluminum					
Chloride					
Color					
Foaming agents					
Iron					
Manganese					
Nickel					
Odor					
Silver					
Sodium					
Sulfate					
TDS					

Contaminant	Method(s) Name/Number and revision	Reference Cite source, year, page	Samples/Mo	Satisfactory Yes	No
Turbidity					
Zinc					

Laboratory _____ **Evaluator** _____

Location _____ **Date** _____

SAMPLE COLLECTION

Item	Comments	Satisfactory Yes	No
Trained Sample Collector			
Representative sampling			
Complete sample form			
Appropriate sampling and preservation			

Item	Comments	Satisfactory Yes	No
Samples exceeding holding times discarded			
VOCs & THMs Hermetic seal			

Laboratory _____ **Evaluator** _____

Location _____ **Date** _____

SAMPLE HANDLING AND PRESERVATION

Contaminant	**Container** material & size	**Preservatives**	**Holding Time** Sample	Extract	**Satisfactory** **Yes**	**No**
Mercury						
Metals						
Silica						
Asbestos						
Cyanide						
Fluoride						
Nitrate						
Nitrite						
Alkalinity						
o-Phosphate						
Total THMs						
VOCs						
Herbicides						
Pesticides						
EDB/DBCP						

Contaminant	**Container** material & size	**Preservatives**	**Holding Time** Sample	Extract	**Satisfactory** **Yes**	**No**
Dioxin						
Other SOCs						
Carbamates						
Diquat						
Endothall						
Glyphosate						
Residual Disinfectants						
Conductivity						
pH						
Temperature						
Turbidity						
Chloride						
Color						
Foaming agents						
Odor						
Sulfate						
TDS						

Chapter V
Critical Elements for Microbiology

Note: This chapter uses the term "must" to refer to certification criteria that are required by the National Primary Drinking Water Regulations which include the approved drinking water methods. The term "should" is used for procedures that, while not specifically required by the regulations, are considered good laboratory practice for quality assurance. To assure the validity of the data, it is critical that laboratories observe both the regulatory and non-regulatory criteria. Certification Officers have the prerogative to refuse certification if the quality control data are judged unsatisfactory or insufficient.

Note: References to *Standard Methods for the Examination of Water and Wastewater* are to the 18th edition (1992)

1. Personnel

1.1 Supervisor/Consultant

The supervisor of the microbiology laboratory should have a bachelor's degree in microbiology, biology, or equivalent. Supervisors who have a degree in a subject other than microbiology should have had at least one college-level microbiology laboratory course in which environmental microbiology was covered. In addition, the supervisor should have a minimum of two weeks training at a Federal agency, State agency, or academic institution in microbiological analysis of drinking water or, 80 hours of on-the-job training in water microbiology at a certified laboratory, or other training acceptable to the State or EPA. If a supervisor is not available, a consultant having the same qualifications may be substituted, as long as the laboratory can document that the consultant is acceptable to the State and is present on-site frequently enough to satisfactorily perform a supervisor's duties.

The laboratory supervisor has the responsibility to insure that all laboratory personnel have demonstrated their ability to satisfactorily perform the analyses to which they are assigned and that all data reported by the laboratory meet the required quality assurance and regulatory criteria.

1.2 Analyst (or equivalent job title)

The analyst should perform microbiological tests with minimal supervision, and have at least a high school education. In addition, the analyst should have a minimum of at least three months of bench experience in water, milk, or food microbiology. The analyst should also have training acceptable to the State (or EPA for non-primacy States), in microbiological analysis of drinking water and a minimum of 30 days of on-the-job training under an experienced analyst. Analysts should take advantage of workshops and training programs that may be available from State regulatory agencies and professional societies. Before analyzing compliance samples, the analyst must demonstrate acceptable results for precision, specificity and satisfactory analysis on unknown samples.

1.3 Waiver of Academic Training Requirement

The certification officer may waive the need for the above specified academic training, on a case-by-case basis, for highly experienced analysts.

1.4 Personnel Records

Personnel records which include academic background, specialized training courses completed and types of microbiological analyses conducted, should be maintained on laboratory analysts

2. Laboratory Facilities

Laboratory facilities should be clean, temperature and humidity controlled, and have adequate lighting at bench tops. They should have provisions for disposal of microbiological waste. Laboratory facilities should have sufficient bench-top area for processing samples; storage space for media, glassware, and portable equipment; floor space for stationary equipment (incubators, water baths, refrigerators, etc.); and associated area(s) for cleaning glassware and sterilizing materials.

3. Laboratory Equipment and Supplies

The laboratory must have the equipment and supplies needed to perform the approved methods for which certification has been requested.

3.1 pH Meter

3.1.1 Accuracy and scale graduations must be within ±0.1 units.

3.1.2 pH buffer aliquots should be used only once.

3.1.3 Electrodes should be maintained according to the manufacturer's recommendations.

QC **3.1.4** pH meters should be standardized before each use period with pH 7.0 and either pH 4.0 or 10.0 standard buffers, whichever range covers the desired pH of the media or reagent. The date and buffers used should be recorded in a log book.

QC **3.1.5** Commercial buffer solution containers should be dated upon receipt, and when opened. Buffers should be discarded before the expiration date.

3.2 *Balance (top loader or pan)*

3.2.1 Balances should have readability of 0.1 g

QC **3.2.2** Balances should be calibrated monthly using ASTM type 1, 2, or 3 weights (minimum of three traceable weights which bracket laboratory weighing needs). (ASTM, 1916 Race St.., Philadelphia, PA 19103) Non-reference weights should be calibrated every six months with reference weights.

QC **3.2.3** Service contracts or internal maintenance protocols and maintenance records should be available. Maintenance should be conducted annually at a minimum. A record of the most recent calibration should be available for inspection. Correction values should be on file and used. A reference weight should be re-certified if it is damaged or corroded.

3.3 Temperature Monitoring Device

3.3.1 Glass, dial, or electronic thermometers must be graduated in 0.5°C increments (0.2°C increments for tests which are incubated at 44.5°C) or less. The fluid column in glass thermometers should not be separated. Dial thermometers that cannot be calibrated should not be used.

QC **3.3.2** Calibrations of glass and electronic thermometers should be checked annually and dial thermometers quarterly, at the temperature used, against a reference National Institute of Standards and Technology (formerly National Bureau of Standards [NBS]) thermometer or one that meets the requirements of NBS Monograph SP 250-23. The calibration factor should be indicated on the thermometer. Also, the laboratory should record the date the thermometer was calibrated and the calibration factor in a QC record book

QC **3.3.3** If a thermometer differs by more than 1°C from the reference thermometer, it should be discarded. Reference thermometers should be recalibrated every three years.

QC **3.3.4** Continuous recording devices that are used to monitor incubator temperature should be recalibrated at least annually. A reference thermometer that meets the specifications described in paragraph 3.3.2 should be used for calibration.

3.4 Incubator Unit

3.4.1 Incubator units must have an internal temperature monitoring device and maintain a temperature of 35° ±0.5°C, and if used, 44.5° ±0.2°C. For non-portable incubators, thermometers should be placed on the top and bottom shelves of the use area with the thermometer bulb immersed in liquid (except for electronic thermometers). If an aluminum block incubator is used, culture dishes and tubes should fit snugly. Laboratories which use the chromogenic/fluorogenic substrate tests with air-type incubators should note the caution indicated in 5.6.8.

QC **3.4.2** Calibration-corrected temperature should be recorded for days in use at least twice per day with readings separated by at least 4 hours.

3.4.3 An incubation temperature of 44.5° ±0.2°C can best be maintained with a water bath equipped with a gable cover and a pump or paddles to circulate water.

3.5 Autoclave

3.5.1 The autoclave should have an internal heat source, a temperature gauge with a sensor on the exhaust, a pressure gauge, and an operational safety valve. The autoclave should maintain a sterilization temperature during the sterilizing cycle and complete an entire cycle within 45 minutes when a 12-15 minute sterilization period is used. The autoclave should depressurize slowly enough to ensure that media will not boil over and bubbles will not form in inverted tubes.

3.5.2 Because of safety concerns and difficulties with operational control, pressure cookers should not be used.

QC **3.5.3** The date, contents, sterilization time and temperature, total time for each cycle, and analyst's initials should be recorded each time the autoclave is used. A copy of the service contract or internal maintenance protocol and maintenance records should be kept. Maintenance should be conducted annually at a minimum. A record of the most recent service performed should be available for inspection.

QC **3.5.4** A maximum-temperature-registering thermometer or continuous recording device should be used during each autoclave cycle to ensure that the proper temperature was reached, and the temperature recorded. Overcrowding should be avoided. Spore strips or ampules should be used monthly to confirm sterilization.

QC **3.5.5** Automatic timing mechanisms should be checked quarterly with a stopwatch or other accurate timepiece or time signal.

3.5.6 Autoclave door seals should be clean and free of caramelized media. Also, autoclave drain screens should be cleaned frequently and debris removed.

3.6 Hot Air Oven

3.6.1 The oven should maintain a stable sterilization temperature of 170-180°C for at least two hours. Only dry items should be sterilized with a hot air oven. Overcrowding should be avoided. The oven thermometer should be graduated in 10°C increments or less, with the bulb placed in sand during use.

QC **3.6.2** The date, contents, sterilization time and temperature of each cycle, and analyst's initials should be recorded.

QC **3.6.3** Spore strip or ampule should be used on a monthly basis to ensure sterility of items.

3.7 Colony Counter

A dark field colony counter should be used to count Heterotrophic Plate Count colonies.

3.8 Conductivity Meter

3.8.1 Meters should be suitable for checking laboratory reagent-grade water and readable in appropriate M units (micromhos or microsiemens per centimeter). Use an instrument capable of measuring conductivity with an error not exceeding 1% or 1 micromho per centimeter, whichever is more lenient.

QC **3.8.2** Cell constant should be determined monthly using a method indicated in Section 2510, "Conductivity," in *Standard Methods*. Monthly calibration checks using an appropriate certified and traceable low-level standard may be substituted for determining the cell constant.

3.8.3 If an in-line unit cannot be calibrated, it should not be used to check reagent-grade water.

3.9 Refrigerator

3.9.1 Refrigerators should maintain a temperature of 1-5°C. Thermometers should be graduated in at least 1°C increments and the thermometer bulb immersed in liquid.

QC **3.9.2** The temperature should be recorded for days in use at least once per day.

3.10 Inoculating Equipment

Sterile metal or disposable plastic loops, wood applicator sticks, sterile swabs, or sterile plastic disposable pipet tips should be used. If wood applicator sticks are used, they should be sterilized by dry heat. The metal inoculating loops and/or needles should be made of nickel alloy or platinum. (For the coliform test and any other oxidase test used for the verification of membrane filter colonies, nickel alloy loops must not be used because they may interfere with the oxidase test).

***3.11 Membrane Filtration Equipment** (if MF procedure is used)*

3.11.1 MF units must be stainless steel, glass, or autoclavable plastic, not scratched or corroded, and must not leak.

QC **3.11.2** If graduation marks on clear glass or plastic funnels are used to measure sample volume, their accuracy should be checked with a standard graduated cylinder, and a record of this calibration check retained. Tolerance should be $\leq$2.5%.

3.11.3 A 10X to 15X stereo microscope with a fluorescent light source must be used to count sheen colonies.

3.11.4 Membrane filters must be approved by the manufacturer for total coliform water analysis. Approval is based on data from tests for toxicity, recovery, retention, and absence of growth-promoting substances. Filters must be cellulose ester, white, gridmarked, 47 mm diameter, and 0.45 μm pore size, or alternate pore sizes if the manufacturer provides performance data equal to or better than the 0.45 μm pore size. Membrane filters must be purchased presterilized or autoclaved for 10 minutes at 121°C before use.

QC **3.11.5** The lot number for membrane filters and the date received should be recorded.

3.12 Culture Dishes (loose or tight lids)

3.12.1 Presterilized plastic or sterilizable glass culture dishes must be used. To maintain sterility of glass culture dishes, stainless steel or aluminum canisters, or a wrap of heavy aluminum foil or char-resistant paper, must be used.

3.12.2 Loose-lid petri dishes should be incubated in a tight-fitting container, e.g., plastic vegetable crisper containing a moistened paper towel to prevent dehydration of membrane filter and medium.

3.12.3 Opened packs of disposable culture dishes should be resealed between use periods.

3.13 Pipets

3.13.1 To sterilize and maintain sterility of glass pipets, stainless steel or aluminum canisters should be used, or individual pipets should be wrapped in char-resistant paper or aluminum foil.

3.13.2 Pipets must have legible markings and should not be chipped or etched.

3.13.3 Opened packs of disposable sterile pipets should be resealed between use periods.

3.13.4 Pipets delivering volumes of 10 mL or less must be accurate within a 2.5% tolerance.

3.13.5 Calibrated micropipetters may be used if tips are sterile. Micropipetters should be calibrated annually and replaced if the tolerance is greater than 2.5%

3.14 Culture Tubes and Closures

3.14.1 Tubes should be made of borosilicate glass or other corrosion-resistant glass or plastic.

3.14.2 Culture tubes and containers should be of sufficient size to contain medium plus sample without being more than three quarters full.

3.14.3 Tube closures should be stainless steel, plastic, aluminum, or screw caps with non-toxic liners. Cotton plugs should not be used.

3.15 Sample Containers

3.15.1 Sample containers must be wide-mouth plastic or non-corrosive glass bottles with non-leaking ground glass stoppers or caps with non-toxic liners that should withstand repeated sterilization, or sterile plastic bags containing sodium thiosulfate. Other appropriate sample containers may be used. The capacity of sample containers should be at least 120 mL (4 oz.).

3.15.2 Glass stoppers must be covered with aluminum foil or char-resistant paper for sterilization.

3.15.3 Glass and plastic bottles that have not been presterilized should be sterilized by autoclaving or, for glass bottles, by dry heat. Empty containers should be moistened with several drops of water before autoclaving to prevent an "air lock" sterilization failure.

3.15.4 If chlorinated water is to be analyzed, sufficient sodium thiosulfate ($Na_2S_2O_3$) must be added to the sample before sterilization to neutralize any residual chlorine in the water sample. Dechlorination is addressed in Section 9060A of Standard Methods.

3.16 Glassware and Plasticware

3.16.1 Glassware must be borosilicate glass or other corrosion-resistant glass and free of chips and cracks. Markings on graduated cylinders and pipets must be legible. Plastic items must be clear and non-toxic to microorganisms.

QC **3.16.2** Graduated cylinders for measurement of sample volumes must have a tolerance of 2.5% or less. In lieu of graduated cylinders, precalibrated containers that have clearly marked volumes of 2.5% tolerance may be used. The calibration of each new lot of precalibrated containers should be validated by selecting at least one container at random and checking the calibration using a previously verified graduated cylinder.

3.17 Ultraviolet lamp (if used)

3.17.1 The unit should be disconnected monthly and the lamps cleaned by wiping with a soft cloth moistened

with ethanol.

QC **3.17.2** If a UV lamp (254 nm) is used for sanitization, the lamp should be tested quarterly with a UV light meter or agar spread plate. The lamp should be replaced if it emits less than 70% of its initial output or if an agar spread plate containing 200 to 250 microorganisms, exposed to the UV light for two minutes, does not show a count reduction of 99%. Other methods may be used to test a lamp if data demonstrate that they are as effective as the two suggested methods.

4. General Laboratory Practices

Although safety criteria are not covered in the laboratory certification program, laboratory personnel should be aware of general and customary safety practices for laboratories. Each laboratory is encouraged to have a safety plan available.

4.1 Sterilization Procedures

4.1.1 Required times for autoclaving at 121°C are listed below. The items must be at temperature for this required amount of time. Except for membrane filters and pads and carbohydrate-containing media, indicated times are minimum times which may necessitate adjustment depending upon volumes, containers, and loads.

Item	Time (min)
Membrane filters & pads	10
Carbohydrate containing media	12-15
Contaminated test materials	30
Membrane filter assemblies	15
Sample collection bottles	15
Individual glassware	15
Dilution water blank	15
Rinse water (0.5 - 1 L)	15-30*

* time depends upon water volume per container and autoclave load

4.1.2 Autoclaved membrane filters and pads and all media should be removed immediately after completion of the sterilization cycle.

4.1.3 Membrane filter equipment must be autoclaved before the beginning of the first filtration series. A filtration series ends when 30 minutes or longer elapses after a sample is filtered.

4.1.4 Ultraviolet light (254 nm) may be used as an alternative to sanitize equipment, if all supplies are presterilized and QC checks are conducted as indicated in paragraph 3.17.2. Ultraviolet light may also be used to control bacterial carry-over between samples during a filtration series.

4.2 Sample Containers

4.2.1 See Section 6.2 for sample preservation.

QC **4.2.2** At least one sample container should be selected at random from each batch of sterile sample bottles or other containers, and sterility confirmed by adding approximately 25 mL of a sterile non-selective broth (e.g., tryptic soy, trypticase soy, or tryptone broth). The broth should be incubated at 35 ±0.5°C for 24 hours and checked for growth. Resterilize if growth is detected.

4.3 Reagent-Grade Water

4.3.1 Only satisfactorily tested reagent water from stills or deionization units may be used to prepare media,

reagents, and dilution/rinse water for performing bacteriological analyses.

QC **4.3.2** The quality of the reagent water should be tested and should meet the following criteria:

Parameter	Limits	Frequency
Conductivity	<2 micromhos/cm (microsiemens/cm) at 25°C	Monthly
Pb, Cd, Cr, Cu, Ni, Zn	Not greater than 0.05 mg/L per contaminant. Collectively, no greater than 0.1 mg/L	Annually
Total Chlorine Residual[1]	<0.1 mg/L	Monthly
Heterotrophic Plate Count[2]	< 500/mL	Monthly
Bacteriological Quality of Reagent Water[3]	Ratio of growth rate 0.8:3.0	Annually

[1] DPD Method should be used. Not required if source water is not chlorinated.

[2] Pour Plate Method. See Standard Methods 9215B.

[3] See Standard Methods, Section 9020B. This bacteriological quality test is not needed for ASTM (ASTM, 1916 Race St.., Philadelphia, PA 19103) Types 1 reagent water, as defined in Standard Methods, Section 1080.

4.4 Dilution/Rinse Water

4.4.1 Stock buffer solution or peptone water should be prepared, as specified in Standard Methods, Section 9050C.

4.4.2 Stock buffers should be autoclaved or filter-sterilized, and containers should be labeled and dated. Stock buffers should be refrigerated. Stored stock buffers should be free from turbidity.

QC **4.4.3** Each batch of dilution/rinse water should be checked for sterility by adding 50 mL of water to 50 mL of a double strength non-selective broth (e.g., tryptic soy, trypticase soy or tryptose broth). Incubate at 35 ±0.5°C for 24 hours and check for growth. Discard if growth is detected.

4.5 Glassware Washing

4.5.1 Distilled or deionized water should be used for final rinse.

QC **4.5.2** A glassware inhibitory residue test (Standard Methods, Section 9020B) should be performed before the initial use of a washing compound and whenever a different formulation of washing compound, or washing procedure, is used. In addition, batches of dry glassware should be spot-checked occasionally for pH reaction, especially if glassware is soaked in alkali or acid (Standard Methods, Section 9020B). These tests will ensure that glassware is at a neutral pH and is free of toxic residue.

4.5.3 Laboratory glassware should be washed with a detergent designed for laboratory use.

5. Analytical Methodology

5.1 General

5.1.1 For compliance samples, laboratories must only use the analytical methodology specified in the Total Coliform Rule (40 CFR 141.21(f)) and the Surface Water Treatment Rule (40 CFR 141.74(a)).

5.1.2 A laboratory must be certified for all analytical methods, indicated below, that it uses for compliance purposes. At a minimum, the laboratory must be certified for one total coliform method and one fecal coliform or *E. coli* method. A laboratory should also be certified for a second total coliform method if one method cannot be used for some drinking waters (e.g., where the water usually produces confluent growth on a plate). In addition, for principal State laboratories and other laboratories that may enumerate heterotrophic bacteria (HPC) for compliance with the Surface Water Treatment Rule, the laboratory must be certified for the Pour Plate Method, the only method approved for heterotrophic bacteria.

5.1.3 Absorbent pads must be saturated with a liquid medium (at least 2 mL of broth) and excess medium removed by "decanting" the plate.

5.1.4 Water samples should be shaken vigorously about 25 times before analyzing.

QC **5.1.5** If no total coliform-positive result occurs during a quarter, the laboratory should perform the coliform procedure using a known coliform-positive, fecal coliform and/or *E. coli*- positive control to spike the sample.

5.1.6 Sample volume analyzed for total coliforms in drinking water must be 100 mL ±2.5 mL.

5.1.7 Media

5.1.7.1 The use of dehydrated or prepared media manufactured commercially is strongly recommended due to concern about quality control. Dehydrated media should be stored in a cool, dry location. Caked or discolored dehydrated media should be discarded.

QC **5.1.7.2** For media prepared in the laboratory, the date of preparation, type of medium, lot number, sterilization time and temperature, final pH, and the technician's initials should be recorded.

QC **5.1.7.3** For liquid media prepared commercially, the date received, type of medium, lot number, and pH verification should be recorded. Medium should be discarded by manufacturer's expiration date.

QC **5.1.7.4** Each new lot of dehydrated or prepared commercial medium should be checked before use with positive and negative culture controls. In addition, each batch of laboratory-prepared medium should include positive and negative culture controls. These control organisms can be stock cultures (periodically checked for purity) or commercially available disks impregnated with the organism. Results should be recorded.

5.1.7.5 Prepared plates may be refrigerated in sealed plastic bags or containers. Because of potential evaporation, they may not be kept for more than two weeks. Each bag or container should include the date prepared or an expiration date. Broth in loose-cap tubes should be stored at <30°C no longer than two weeks. Broth in tightly capped tubes should be stored at <30°C no longer than three months.

When ready to use, the refrigerated sterilized medium should be incubated overnight at room temperature; media with growth should be discarded.

QC **5.1.8** Laboratories are encouraged to perform parallel testing between a newly approved test and another EPA-approved procedure for enumerating total coliforms for at least several months and/or over several seasons to assess the effectiveness of the new test for the wide variety of water types submitted for analysis. During this testing, spiking the samples occasionally with sewage or a pure culture may be necessary to ensure that some of the tests are positive.

5.2 Membrane Filter (MF) Technique (for total coliforms in drinking water)

5.2.1 Media

5.2.1.1 M-Endo Medium broth or agar (also known as M-Endo broth MF and M-Coliform Broth) or LES Endo agar (also known as M-Endo Agar LES) must be used in the single step or enrichment techniques. Ensure that ethanol used in the rehydration procedure is not denatured. Medium must be prepared in a sterile flask and a boiling water bath must be used or, if constantly attended, a hot plate with a stir bar may be used, to bring the medium just to the boiling point. The medium must not be boiled. pH must be 7.2 ±0.2 for LES Endo agar and 7.2 ±0.1 for M-Endo medium.

5.2.1.2 MF broth must be refrigerated no longer than 96 hours, poured MF agar plates no longer than two weeks, and ampuled M-Endo broth in accordance with the manufacturer's expiration date. Broth, plates, or ampules should be discarded earlier if growth or surface sheen is observed.

QC **5.2.1.3** MF sterility check should be conducted on each funnel in use at the beginning and the end of each filtration series by filtering 20-30 mL of dilution water through the membrane filter and testing for growth. If the control indicates contamination, all data from affected samples must be rejected and an immediate resampling should be requested. A filtration series ends when 30 minutes or more elapse between sample filtrations.

5.2.2 To prevent carry-over, the filtration funnels must be rinsed with two or three 20-30 mL portions of water after each sample filtration.

5.2.3 Inoculated medium must be incubated at 35°±0.5°C for 22-24 hours.

5.2.4 All samples resulting in confluent or TNTC (too numerous to count) growth must be invalidated unless total coliforms are detected. If no total coliforms are detected, record as "confluent growth" or "TNTC" and request an additional sample from the same sampling site. Confluent growth is defined as a continuous bacterial growth covering the entire membrane filter without evidence of sheen colonies (total coliforms). TNTC is defined as greater than 200 colonies on the membrane filter in the absence of detectable coliforms. Laboratories must not invalidate samples when the membrane filter contains at least one sheen colony. (Before invalidation, the laboratory may perform a verification test on the total coliform-negative culture, i.e., on confluent or TNTC growth, and a fecal coliform/*E. coli* test. If the verification test is total coliform-positive, the sample must be reported as total coliform-positive. If the test is total coliform-negative, the sample must be invalidated. A fecal coliform/*E. coli*-positive result is considered a total coliform-positive, fecal coliform/*E.coli*-positive sample, even if the initial and/or verification total coliform test is negative.)

5.2.5 All sheen colonies (pick all sheen colonies up to a maximum of five) must be verified using either single strength lactose broth (LB) or lauryl tryptose broth (LTB) and single strength brilliant green lactose bile broth (BGLBB), or EPA-approved cytochrome oxidase and ß-galactosidase rapid test procedure. Individual colonies can be transferred with a sterile needle or loop, or applicator stick. When picking individual colonies, different morphological types of up to five red questionable sheen colonies and/or red non-sheen colonies per sample must be verified to include different types. Alternatively, wipe the entire surface of the membrane filter with a sterile cotton swab.

5.2.6 When EC Medium or EC Medium + MUG is used, the colonies must be transferred by employing one of the options specified by paragraph 141.21(f)(5). For the swab technique, a single swab can be used to inoculate a presumptive total coliform-positive culture into up to three different media (e.g., EC or EC-MUG Medium, LTB, and BGLBB, in that order).

5.3 ***Multiple Tube Fermentation Technique (MTF or MPN)*** *(for total coliforms in drinking water)*

5.3.1 Various testing configurations can be used (CFR141.21(f)(3) , see Appendix G), as long as a total sample volume of 100 mL is examined for each test.

5.3.2 Media

5.3.2.1 LTB (also known as lauryl sulfate broth) must be used in the presumptive test and BGLBB in the confirmed test. LB may be used in lieu of LTB (40 CFR 141.21(f)(3)) if the laboratory conducts at least 25 parallel tests between this medium and LTB using the waters normally tested and this comparison demonstrates that the false-positive rate and false-negative rate for total coliforms, using LB, is less than 10%. This comparison should be documented and the records retained. The pH must be 6.8 ±0.2 for LTB, and 7.2 ±0.2 for BGLBB.

5.3.2.2 The test medium concentration must be adjusted to compensate for the sample volume so that the resulting medium after sample addition is single strength. If a single 100-mL sample volume is used, the inverted vial should be replaced with an acid indicator (bromcresol purple) to prevent problems associated with gas bubbles in large inverted tubes. The media must be autoclaved at 121°C for 12-15 minutes.

5.3.2.3 Sterile medium in tubes must be examined to ensure that the inverted vials, if used, are free of air bubbles and are at least one-half to two-thirds covered after the water sample is added.

5.3.2.4 If MTF media are refrigerated after sterilization, they should be incubated overnight at room temperature before use. Tubes/bottles showing growth and/or bubbles should be discarded. If prepared broth media are stored, they should be maintained in the dark at <30°C no longer than three months for screw-cap tubes/bottles and two weeks for tubes/bottles with loose-fitting closures. Media should be discarded if evaporation exceeds 10% of the original volume.

5.3.3 After the medium is inoculated, it must be incubated at 35°±0.5°C for 24 ± two hours. If no gas or acid is detected, it must be incubated for another 24 hours.

5.3.4 All samples that produce a turbid culture (i.e., heavy growth, opaque) in the absence of gas/acid production, in LTB or LB, must be invalidated. The laboratory must collect, or request that the system collect, another sample from the same location as the original invalidated sample. (Before invalidation, the laboratory may perform a confirmed test on the total coliform-negative culture. If the confirmed test is total coliform-positive, the sample must be reported as such. If the test is total coliform-negative, the sample must be invalidated.)

5.3.5 24- and 48-hour gas-positive or acid-positive tubes must be confirmed using BGLBB.

5.3.6 A completed test is not required.

5.3.7 If the MTF test is used on water supplies that have a history of confluent growth or TNTC by the MF procedure, all presumptive tubes with heavy growth without gas/acid production must be submitted to the confirmed test and a fecal coliform/*E. coli* test to check for coliform suppression. (The Total Coliform Rule requires that laboratories invalidate presumptive tubes with heavy growth without gas production and request that the system provide another water sample within 24 hours. However, if the confirmed test is coliform-positive, the laboratory may consider the first sample as coliform-positive. In contrast, if the confirmed test is coliform-negative, the laboratory must not consider this sample as coliform-negative, because high levels of non-coliform bacteria in the presumptive tubes may have injured, killed, or suppressed the growth of any coliforms in the sample. A fecal coliform/*E. coli* positive result is considered a total coliform-positive, fecal coliform/*E. coli*-positive sample, even if the presumptive and/or confirmed total coliform test is negative.)

5.4 Presence-Absence (P-A) Coliform Test (for drinking water)

5.4.1 Medium

5.4.1.1 Six-times formulation strength may be used if the medium is filter-sterilized rather than

autoclaved.

5.4.1.2 The medium must be autoclaved for 12 minutes at 121°C. Total time in the autoclave should be less than 30 minutes. Space should be allowed between bottles. The pH must be 6.8 ±0.2.

5.4.1.3 If prepared medium is stored, it should be maintained in a culture bottle at <30°C in the dark for no longer than three months. If evaporation exceeds 10% of original volume earlier, the medium should be discarded.

5.4.2 A 100-mL sample must be inoculated into a P-A culture bottle.

5.4.3 Medium must be incubated at 35° ±0.5°C and observed for a yellow color (acid) after 24 and 48 hours.

5.4.4 Yellow cultures must be confirmed in BGLBB and a fecal coliform/*E. coli* test must be conducted.

5.4.5 All samples which produce a non-yellow turbid culture in P-A medium must be invalidated. The laboratory must collect, or request that the system collect, another sample from the same location as the original invalidated sample. (Before invalidation, the laboratory may perform a confirmed test on the total coliform negative culture and/or a fecal coliform/*E. coli* test. If the confirmed test is total coliform-positive, the sample must be reported as such. If the confirmed test is negative, the sample must be invalidated. A fecal coliform/*E. coli* positive result is considered a total coliform-positive, fecal coliform/*E. coli* positive sample, even if the presumptive and/or confirmed total coliform test is negative.)

5.5 Fecal Coliform Test (using EC Medium for fecal coliforms in drinking water or source water, or A-1 Medium for fecal coliforms in source water only)

5.5.1 EC medium must be used to determine whether a total coliform-positive culture taken from the distribution system contains fecal coliforms, in accordance with the Total Coliform Rule. The laboratory must transfer each total coliform-positive culture from a presumptive tube/bottle, or each presumptive total coliform-positive colony (five such colonies minimum) unless a cotton swab is used, to at least one tube containing EC Medium with an inverted vial, as specified by §141.21(f)(5).

5.5.2 EC Medium may be used to enumerate fecal coliforms in source water, in accordance with the Surface Water Treatment Rule. Initially, conduct an MTF test (presumptive phase). Three sample volumes of source water (10, 1 and 0.1 mL), 5 or 10 tubes/sample volume, should be used. A culture from each total coliform-positive tube must be transferred to a tube containing EC Medium with an inverted vial.

5.5.2.1 Medium must be autoclaved for 12-15 minutes at 121°C. The pH must be 6.9 ±0.2.

5.5.2.2 Inverted vials should be examined to ensure that they are free of air bubbles. The inverted vial must be at least one-half to two-thirds covered after the sample is added.

5.5.2.3 If prepared medium is stored, it should be maintained in the dark at <30°C. Prepared medium stored in tubes with loose-fitting closures should be used within two weeks. Prepared medium stored in tightly closed screw type tubes may be kept up to three months. If the medium is stored in a refrigerator, it should be incubated overnight at room temperature before use; tubes that show growth and/or bubbles should be discarded.

5.5.3 A-1 Medium may be used as an alternative to EC Medium to enumerate fecal coliforms in source water, in accordance with the Surface Water Treatment Rule. A-1 Medium must not be used for drinking water samples. Three sample volumes of source water (10, 1 and 0.1 mL), 5 or 10 tubes/sample volume, should be used. Unlike EC Medium, A-1 Medium can be directly inoculated with a water sample.

5.5.3.1 Medium must be sterilized by autoclaving at 121°C for 10 minutes. The pH must be 6.9 ±0.1.

5.5.3.2 Inverted vials should be examined to ensure that they are free of air bubbles.

5.5.3.3 Loose-cap tubes should be stored in dark at room temperature not more than two weeks. A-1 Medium may be held up to three months in a tightly closed screwcap tube in the dark at <30°C.

5.5.4 The water level of the water bath must be above the upper level of the medium in the culture tubes.

5.5.5 EC Medium must be incubated at 44.5° ±0.2°C for 24 ±2 hours. A-1 Medium must be incubated at 35° ±0.5°C for three hours, then at 44.5° ±0.2°C for 21 ±2 hours.

5.5.6 Any amount of gas detected in the inverted vial of a tube that has turbid growth must be considered a fecal coliform-positive test.

5.6 Chromogenic/fluorogenic substrate tests (MMO-MUG test [Colilert test] for total coliforms in source water and total coliforms and E. coli in drinking water; Colisure test for total coliforms and E. coli in drinking water)

5.6.1 Media

5.6.1.1 These media must not be prepared from basic ingredients, but rather purchased from a commercially available source.

5.6.1.2 The media must be protected from light. Colisure medium must be refrigerated until use and brought to room temperature before adding the sample.

5.6.1.3 Some lots of fluorogenic media have been known to autofluoresce. Therefore, each lot of medium should be checked before use with a 366-nm ultraviolet light with a 6-watt bulb. If the media exhibit faint fluorescence, the laboratory should use another lot that does not fluoresce. If the samples plus a medium exhibit a color change before incubation, it should be discarded and another batch of medium used.

QC **5.6.1.4** For each lot of medium, a quality control check must be performed by inoculating sterile water containing the medium with a MUG-positive *E. coli* strain, a MUG-negative coliform, and a non-coliform and analyzing them.

QC **5.6.1.5** Laboratories may also use Quanti-Tray test or Quanti-Tray 2000 test for drinking water and source waters. Both tests use the Colilert medium. If the Quanti-Tray or Quanti-Tray 2000 test is used, the sealer should be checked monthly by adding a dye (e.g., bromcresol purple) to the water. If dye is observed outside the wells, another sealer should be obtained.

5.6.2 A glass bottle that contains inoculated medium should be checked with a 366-nm ultraviolet light source with a 6-watt bulb. If fluorescence is observed before incubation, do not use.

5.6.3 For enumerating total coliforms in source water with the Colilert test, 5 or 10 tube MTF, Quanti-Tray or Quanti-Tray 2000 must be used for each sample dilution tested. Dilution water (for the chromogenic/fluorogenic substrate test only), if used, must be sterile dechlorinated tap water, deionized water, or distilled water.

5.6.4 For determining the presence of total coliforms in drinking water by a chromogenic/fluorogenic substrate test, laboratories must use 10 tubes, each containing 10 mL of water sample, or a single vessel

containing 100 mL of water sample.

5.6.5 For the Colilert test, samples must be incubated at 35 ±0.5°C for 24 hours. A yellow color in the medium equal to or greater than the reference comparator indicates the presence of total coliforms and must be reported as a total coliform positive. If the sample is yellow, but lighter than the comparator, it must be incubated for another four hours (do not incubate more than 28 hours total). If the color is still lighter than the reference comparator at 28 hours, the sample should be reported as negative. Laboratories that use the Colilert-18 test must incubate for 18 hours.

5.6.6 For the Colisure test, samples must be incubated at 35 ±0.5°C for 28 hours. If an examination of the results at 28 hours is not convenient, then results may be examined at any time between 28 and 48 hours. If the medium changes from a yellow color to a magenta color, the sample must be reported as E. *coli* positive.

5.6.7 For *E. coli* testing, the laboratory must place all total coliform-positive bottles/tubes under an ultraviolet lamp (366 nm, 6-watt) in a darkened room. If *E. coli* is present, the medium will emit a blue fluorescence.

QC **5.6.8** Air-type incubators, especially small ones, may not bring a cold 100-mL water sample(s) to the specified incubation temperature of 35°C for several hours. This problem may be further aggravated if several cold water samples are placed in the incubator at the same time. The problem may cause false-negative results with the chromogenic/fluorogenic substrate tests. Therefore, laboratories with air-type incubators should check the time it takes for a 100-mL water sample (or a set of 100-mL water samples, depending on normal use) to reach 35°C, and ensure that the specified incubation period at that temperature is followed. This check should be repeated whenever there is a significant change in the sample load.

5.6.9 The Colilert/Colisure tests must not be used to confirm total coliforms on membrane filters. The filtration step not only concentrates coliforms, but also non-coliforms and turbidity, which at high levels, can suppress coliforms or cause false-positive results in the chromogenic/fluorogenic substrate test.

5.6.10 The Colilert/Colisure tests must not be used to confirm total coliforms in the MTF or Presence-Absence (P-A) coliform test. High densities of non-coliforms in the inoculum may overload the chromogenic/fluorogenic substrate test suppressant reagent system and cause false positive results.

5.7 EC Medium + MUG Test (for E. *coli)*

5.7.1 If EC medium + MUG is used, a total coliform-positive culture must be transferred from a presumptive tube/bottle or colony to EC medium + MUG, as specified by §141.21(f)(5).

5.7.2 Medium

5.7.2.1 MUG may be added to EC Medium before autoclaving. EC Medium + MUG is also available commercially. The final MUG concentration must be 50 μg/mL. The pH must be 6.9 ±0.2.

5.7.2.2 The inverted vial may be omitted, because gas production is not relevant to the test, and the use of an inverted vial may cause confusion on test interpretation.

5.7.2.3 Test tubes and autoclaved medium should be tested before use with a 366-nm ultraviolet light to ensure they do not fluoresce. If fluorescence is exhibited, non-fluorescing tubes or another lot of medium that does not fluoresce should be used; alternatively, a MUG-positive *E. coli* and MUG-negative (e.g., uninoculated) control should be performed for each analysis.

5.7.2.4 If prepared medium is stored, it should be maintained in the dark at <30°C. Prepared medium stored in tubes with loose-fitting closures should be used within two weeks. Prepared medium stored in tightly closed screw type tubes may be kept up to three months. Tubes with

growth should be discarded.

QC **5.7.2.5** In accordance with paragraph 5.1.7.5, control cultures should be incubated at 35° ±0.5°C for 24 hours in LTB. A loopful should be transferred to EC Medium + MUG and then incubated at 44.5°±0.2°C for 24 hours. The results should be read and recorded.

5.7.3 The water level of the water bath must be above the upper level of the medium.

5.7.4 The medium must be incubated at 44.5°±0.2°C for 24 ±2 hours.

5.7.5 Fluorescence must be checked using an ultraviolet lamp (366 nm) with a 6-watt bulb in a darkened room. Laboratories should ensure that a weak auto-fluorescence of medium, if present, is not misinterpreted as positive for *E. coli*. (If uncertain, a MUG-positive *E. coli* and MUG negative (e.g., uninoculated) control for each analysis should be used whenever the medium autofluoresces.)

5.8 Nutrient Agar + MUG Test (for* E. *coli)

5.8.1 Medium

5.8.1.1 Medium must be autoclaved in 100-mL volumes at 121°C for 15 minutes. MUG may be added to Nutrient Agar before autoclaving. Nutrient Agar + MUG is also available commercially. The final MUG concentration must be 100 μg/mL. The pH must be 6.8 ±0.2.

5.8.1.2 If sterile medium is stored, the medium should be refrigerated in petri dishes, in a plastic bag or tightly closed container, and used within two weeks. Before use, refrigerated sterilized medium should be incubated overnight at room temperature; plates with growth should be discarded.

QC **5.8.1.3** Positive and negative controls should be tested as stated in paragraph 5.1.7.5. Filter or spot-inoculate control cultures onto a membrane filter on M-Endo LES agar or M-Endo broth or agar, and incubate at 35°C for 24 hours. Then transfer the filter to Nutrient Agar + MUG and incubate at 35°C for another four hours. The results should be read and recorded.

5.8.2 The membrane filter containing coliform colony(ies) must be transferred from the total coliform medium to the surface of Nutrient Agar + MUG medium. Each sheen colony should be marked with a permanent marker on the lid. Also, the lid and the base should be marked with a line to realign the lid should it be removed. A portion of the colony may be transferred with a needle to the total coliform verification test before transfer to Nutrient Agar + MUG or after the four-hour incubation time. Another method is to swab the entire membrane filter surface after the 4-hour incubation time onto the Nutrient Agar + MUG medium, with a sterile cotton swab, and transfer to a total coliform verification test.

5.8.3 Inoculated medium must be incubated at 35°±0.5C° for four hours.

5.8.4 Fluorescence must be checked using an ultraviolet lamp (366 nm) with a 6-watt bulb in a darkened room. Any amount of fluorescence in a halo around a sheen colony should be considered positive for *E. coli*.

5.9 Heterotrophic Plate Count *(for enumerating heterotrophs in drinking water)*

5.9.1 The Pour Plate Method must be used for enumerating heterotrophic bacteria in drinking water under §141.74(a)(3), (also listed in Appendix G) and should be used for testing reagent grade water. For systems that have been granted a variance from the Total Coliform Rule's maximum contaminant level (see variance criteria in the preamble of FR 56:1556-1557, January 15, 1991), any method in Standard Methods section 9215, "Heterotrophic Plate Count," may be used with R2A medium, for enumerating heterotrophic bacteria in drinking water.

5.9.2 Media (includes plate count agar [tryptone glucose extract agar] and R2A agar)

5.9.2.1 Final pH values must be 7.0 ± 0.2 for plate count agar and 7.2 ± 0.2 for R2A agar.

5.9.2.2 (For Pour Plate Method) Melted agar must be tempered at 44-46°C in waterbath before pouring. Melted agar should be held no longer than three hours. Sterile agar medium should not be melted more than once.

5.9.2.3 (For Spread Plate Method) 15 mL of R2A agar medium (or other medium) should be poured into a petri dish (100 x 15 mm or 90 x 15 mm) and allowed to solidify.

5.9.2.4 Refrigerated medium may be stored in bottles or in screw-capped tubes for up to six months, or in petri dishes for up to two weeks. Prepared petri dishes with R2A medium may be stored for up to one week.

5.9.3 For most potable water samples, countable plates can be obtained by plating 1.0 mL and/or 0.1 mL volumes of the undiluted sample. At least duplicate plates per dilution should be used.

5.9.4 (For Pour Plate Method) The sample must be aseptically pipetted onto the bottom of a 100 mm x 15 mm petri dish (100 x 15 mm or 90 x 15 mm). Then, 12-15 mL of tempered melted (44-46ºC) agar must be added to each petri dish. The sample and melted agar must be mixed carefully to avoid spillage. After agar plates have solidified on a level surface, the plates must be inverted and incubated at 35º ± 0.5ºC for 48 ±3 hours. Plates should be stacked no more than four high and arranged in the incubator to allow proper air circulation and to maintain uniform incubation temperature.

5.9.5 (For Spread Plate Method) 0.1 or 0.5 mL of the sample (or dilution) must be pipetted onto the surface of the predried agar in the plate, and then spread over the entire surface of the agar using a sterile bent glass rod. The inoculum must be absorbed completely by the agar before the plate is inverted and incubated. The plate must be incubated at 20-28°C for 5-7 days.

5.9.6 (For Membrane Filter Technique) The volume to be filtered must yield between 20-200 colonies. The filter is transferred to a petri dish containing 5 mL of solidified R2A medium, and incubated at 20-28°C for 5-7 days. If plates with loose-fitting lids are used, plates must be placed in a plastic box with a close fitting lid containing moistened paper towels. Paper towels should be rewetted as necessary to maintain moisture. Colonies must be counted using a stereoscopic microscope at 10-15X amplification.

5.9.7 (For Pour Plate and Spread Plate Techniques) Colonies must be counted manually using a darkfield colony counter. In determining sample count, laboratories must only count plates having 30 to 300 colonies, except for plates inoculated with 1.0 mL of undiluted sample. Counts less than 30 for such plates are acceptable. (Fully automatic colony counters are not suitable because of the size and small number of colonies observed when potable water is analyzed for heterotrophic bacteria).

QC **5.9.8** Each batch or flask of agar should be checked for sterility by pouring a final control plate. Data should be rejected if control is contaminated.

5.10 Membrane Filter Technique (for enumerating total coliforms in source water)

5.10.1 The same as paragraphs 5.2.1-5.2.4 except that in paragraph 5.2.4, laboratories must invalidate any sample which results in confluent growth or TNTC, even when total coliform colonies are present and because coliform density must be determined.

5.10.2 To optimize counting, appropriate sample dilutions must be used to yield 20 to 80 total coliform colonies per membrane.

5.10.3 Initial counts must be adjusted based upon verified data, as in Standard Methods, Section 9222B.

QC **5.10.4** If two or more analysts are available, each analyst should count the total coliform colonies on the same membrane, monthly. Colony counts should agree within 10%.

5.11 ***Multiple Tube Fermentation Technique*** *(for enumerating total coliforms in source water)*

5.11.1 Laboratories must use at least 3 series of 5 tubes each with appropriate sample dilutions of source water (e.g., 0.1 mL, 0.01 mL, 0.001 mL).

5.11.2 Follow the instructions in paragraphs 5.3.1 - 5.3.6, except for 5.3.4 on sample invalidation.

5.11.3 All samples that produce a turbid culture (i.e., heavy growth, opaque) in the absence of gas/acid production, in LTB or LB, must be invalidated. The laboratory must collect, or request that the system collect, another sample from the same location as the original invalidated sample. The laboratory may use another method to test the second sample. Alternatively, if a sample produces a turbid culture in the absence of gas production, a confirmed test may be performed. If the confirmed test is total coliform-positive, the MPN should be reported. If a confirmed test is total coliform-negative, the sample must be invalidated and another one requested.

5.12 ***Fecal Coliform Membrane Filter Procedure*** *(for enumerating fecal coliforms in source water)*

5.12.1 Medium (m-FC broth/agar)

5.12.1.1 m-FC broth (with or without agar) must be prepared by bringing it just to the boiling point. However, medium must not be autoclaved. Final pH must be 7.4 ±0.2.

5.12.1.2 When stored, prepared medium should be refrigerated. Broth medium must be discarded after 96 hours and poured an agar medium in petri dishes should be discarded after two weeks. Medium should be discarded earlier if growth is observed.

5.12.2 Appropriate sample volumes to yield 20-60 fecal coliform colonies per membrane for at least one dilution must be used.

QC **5.12.3** To prevent carry-overs, the filtration funnels must be rinsed with two or three 20-30 mL portions of sterile rinse water after each sample filtration.

QC **5.12.4** A sterility check should be conducted at the beginning and end of each filtration series by filtering 20-30 mL of dilution water through the membrane filter. If the control indicates contamination, all data from affected samples should be rejected and immediate resampling requested.

5.12.5 Inoculated medium must be incubated at 44.5° ±0.2°C for 24 ±2 hours.

QC **5.12.6** If two or more analysts are available, each analyst should count fecal coliform colonies on the same membrane monthly. Colony counts should agree within 10%.

6. Sample Collection, Handling, and Preservation

Paragraphs 6.1-6.5 are applicable to those laboratories that collect samples. However, all laboratories should make an effort to ensure proper sample collection; all laboratories are responsible for paragraph 6.6.

6.1 ***Sample Collector***

The sample collector should be trained in aseptic sampling procedures and, if required, approved by the appropriate regulatory authority or its designated representative.

6.2 Sampling

(For drinking water) Samples must be representative of the water distribution system. Water taps used for sampling should be free of aerators, strainers, hose attachments, mixing type faucets, and purification devices. Cold water taps should be used. The service line must be cleared before sampling by maintaining a steady water flow for at least two minutes (until the water changes temperature). At least 100 mL of sample must be collected, allowing at least a 1-inch air space to facilitate mixing of the sample by shaking. Immediately after collection, a sample information form should be completed (see paragraph 6.5). See Section 3.15.4 regarding sample dechlorination.

Source water samples must be representative of the source of supply, collected not too far from the point of intake, but at a reasonable distance from the bank or shore. The sample volume should be sufficient to perform all the tests required.

6.3 Sample Icing

Samplers are encouraged, but not required, to hold drinking water samples at <10°C during transit to the laboratory. Source water samples must be held at <10°C (see Standard Methods, Section 9060B).

6.4 Sample Holding/Travel Time

The time from sample collection to initiation of analysis for total coliforms, fecal coliforms, or *E. coli* in drinking water must not exceed 30 hours. The time from sample collection to initiation of analysis for total coliforms and fecal coliforms in source water, and heterotrophic bacteria in drinking water must not exceed eight hours (see Section 9060B in *Standard Methods).* All samples received in the laboratory should be analyzed on the day of receipt. If the laboratory receives the sample late in the day, the sample may be refrigerated overnight as long as analysis begins within 30 hours of sample collection.

6.5 Sample Information Form

After collection, the sampler should enter on a sample information form, in indelible ink, the following information:

- Name of system (public water system site identification number, if available)
- Sample identification (if any)
- Sample site location
- Sample type (e.g., routine distribution system sample, repeat sample, raw or process water, other special purpose sample)
- Date and time of collection
- Analysis required
- Disinfectant residual
- Name of sampler and organization (if not the water system)
- Sampler's initials
- Person(s) transporting the samples from the system to the laboratory (if not the sampler)
- Transportation condition (e.g., <10°C, protection from sunlight). If a commercial shipper was used, shipping records should be available.
- Any remarks

6.6 Chain-of-Custody

Sample collectors and laboratories must follow applicable State regulations pertaining to chain-of-custody. An example of such a plan is provided in Appendix A.

7. Quality Assurance

A written QA plan should be prepared and followed (see Chapter III). The QA plan should be available for inspection by the certification officer.

8. Records and Data Reporting

8.1 Legal Defensibility: Compliance monitoring data should be made legally defensible by keeping thorough and accurate records. The QA plan and/or SOPs should describe the policies and procedures used by the facility for record retention and storage. If samples are expected to become part of a legal action, chain-of-custody procedures should be used (See Appendix A).

8.2 Maintenance of Records: Public Water Systems are required to maintain records of microbiological analyses of compliance samples for five years (40 CFR 141.33). The laboratory should maintain easily accessible records for five years or until the next certification data audit is complete, whichever is longer. The client water system should be notified before disposing of records so they may request copies if needed. This includes all raw data, calculations, and quality control data. These data files may be either hard copy, microfiche or electronic. Electronic data should always be backed up by protected tape or disk or hard copy. If the laboratory changes its computer hardware or software, it should make provisions for transferring old data to the new system so that it remains retrievable within the time frames specified above. Data which is expected to become part of a legal action will probably need to be maintained for a longer period of time. Check with your legal counsel. See Appendix H, section 3.0, and *Good Automated Laboratory Practices*, EPA 2185, Office of Information Management, Research Triangle Park, NC 27711, 8/10/95.

8.3 Sampling Records: Data should be recorded in ink with any changes lined through such that original entry is visible. Changes should be initialed and dated The following information should be readily available in a summary or other record(s):

8.3.1 Sample information form, from 6.5 above;
8.3.2 Date and time of sample receipt by the laboratory; name of carrier
8.3.3 Name of laboratory person receiving the sample;
8.3.4 If a deficiency in the condition of the sample is noted, the sample, at a minimum, is flagged;
8.3.5 If sample transit time exceeds 30 hours (8 hours for source water samples), sample must be tagged;

8.4 *Analytical Records*: Data should be recorded in ink with any changes lined through such that original entry is visible. Changes should be initialed and dated The following information should be readily available in a summary or other record(s):

8.4.1 Laboratory sample identification;
8.4.2 Date and time analysis begins;
8.4.3 Laboratory and person(s) responsible for performing analysis;
8.4.4 Analytical technique or method used;
8.4.5 All items marked QC;
8.4.6 Results of analyses.

8.5 Preventive Maintenance

Laboratories should maintain preventive maintenance and repair activities records for all instruments and equipment (including pH meters, analytical balances, incubators, refrigerators, autoclaves and water baths). Records should be kept for five years.

9. Action Response to Laboratory Results

9.1 Testing Total Coliform-Positive Cultures

For the Total Coliform Rule, laboratories must test all total coliform-positive cultures for the presence of either fecal coliforms or *E. coli*.

9.2 Notification of Positive Results

For the Total Coliform Rule, laboratories must promptly notify the proper authority of a positive total coliform, fecal coliform, or *E. coli* result, so that appropriate follow-up actions (e.g., collection of repeat samples) can be conducted (see CFR 141.21(b) and (e), 40 CFR 141.31, etc.) A total coliform-positive result is based on a confirmed phase for the Multiple Tube Fermentation Technique and Presence-Absence (P-A) Coliform Test, or verified test for Membrane Filter Technique. No requirement exists for confirmation of positive Colilert/Colisure tests, fecal coliform test, or *E. coli* tests. In those rare cases where a presumptive total coliform-positive culture does not confirm/verify as such, but is found to be fecal coliform or *E. coli* positive, the sample is considered total coliform-positive and fecal coliform/*E. coli* positive.

9.3 Invalidation of Total Coliform-Negative Sample

For the Total Coliform Rule, the laboratory must promptly notify the proper authority (usually the water system) when results indicate that non-coliforms may have interfered with the total coliform analysis, as described in 40 CFR 141.21(c)(2).

MICROBIOLOGY LABORATORY ANALYSIS REVIEW CHECKLIST

LABORATORY_____

ADDRESS_____

_____

_____

_____

_____

TELEPHONE NUMBER / FAX NUMBER_____

CONDUCTED BY_____

DATE_____

NAMES/TITLES/RESPONSIBILITIES OF KEY PERSONNEL INTERVIEWED

_____

_____

_____

_____

_____

_____

Element	Yes	No	Comments
1. PERSONNEL			
1.1 Supervisor/Consultant			
Supervisor of analyst has a bachelor's degree in microbiology, biology, or equivalent with at least one college-level laboratory course in environmental microbiology, and has a minimum of two weeks course training or 80 hours of on-the-job training in water microbiology at a certified laboratory, or other training acceptable to the State or EPA			
If supervisor not available, consultant with same training and experience substituted, acceptable to the State, and present on-site frequently enough to satisfactorily perform a supervisor's duties			
1.2 Analyst (or equivalent job title)			
Analyst has a high school education, 3 months bench experience in microbiology, training in microbiological analysis of drinking water acceptable to the State (or EPA) and a minimum of 30 days on-the-job training under an experienced analyst			
Analyst demonstrated acceptable results for precision, specificity, and satisfactory analysis on unknown samples before analyzing compliance samples			
1.3 Waiver of Academic Training Requirement			
Need for specified academic training waived for highly experienced analysts			
1.4 Personnel Records			
Personnel records maintained on laboratory analysts include academic background, specialized training courses completed and types of microbiological analyses conducted			
2. LABORATORY FACILITIES			
Laboratory facilities clean, temperature and humidity controlled, with adequate lighting at bench top			
Sufficient space available for processing samples, bench top equipment, storage, cleaning glassware and sterilizing materials			
Provisions made for disposal of microbiological wastes			
3. LABORATORY EQUIPMENT AND SUPPLIES			
3.1 pH meter			
Accuracy and scale graduations within ± 0.1 units			
Buffer aliquot used only once			

Element	Yes	No	Comments
Electrodes maintained according to manufacturer's recommendations			
QC Meter standardized each use period with pH 7.0 and either 4.0 or 10.0 buffers, with date and buffers used recorded in log book			
QC Commercial buffer solutions dated when received and opened and discarded before expiration date			
3.2. Balance (top loader or pan)			
Readability of 0.1 g			
QC Calibrated monthly using ASTM type 1, 2, or 3 weights (minimum 3 traceable weights which bracket laboratory weighing needs)			
QC Non-reference weights calibrated every six months with reference weights			
QC Annual service contract or internal maintenance protocol established, records available of most recent recalibration, and correction values on file and used			
QC Reference weight recertified if damaged or corroded			
3.3 Temperature Monitoring Device			
Temperature monitoring devices graduated in 0.5°C increments (0.2°C increments for tests which are incubated at 44.5°C) or less			
No separation in fluid column of glass thermometer			
No dial thermometers used which cannot be adjusted			
QC Glass and electronic thermometers calibrated annually, dial thermometers quarterly, at the temperature used against reference NIST thermometer or one meeting the requirements of NBS Monograph SP 250-23			
QC Calibration factor marked on thermometer and calibration date and calibration factor recorded in QC record book			
QC Thermometer discarded if off more than 1°C from reference thermometer, reference thermometers recalibrated every 3-5 years			
QC Continuous recording devices used to monitor incubator temperature recalibrated annually as above			
3.4 Incubator Unit			
Incubator units have an internal temperature monitoring device and maintain temperature of 35 ± 0.5°C, and if used, 44.5 ± 0.2°C			

Element	Yes	No	Comments
Thermometers placed on top and bottom shelves of use area in non-portable incubators, with thermometer bulb immersed in liquid (except for electronic thermometers)			
For aluminum block incubator, culture dishes and tubes fit snugly			
QC Calibration-corrected temperature recorded twice daily for days in use, readings separated by at least four hours			
Water bath equipped with gable cover and pump or paddles used to circulate water (recommended for maintaining 44 ± 0.2°C)			
3.5 Autoclave			
Autoclave has internal heat source, temperature gauge with sensor on exhaust, pressure gauge, and operational safety valve			
Maintains sterilization temperature during cycle and completes entire cycle within 45 minutes when 12-15 minute sterilization period used			
Depressurizes slowly enough to ensure media will not boil over and bubbles will not form in inverted tubes			
Pressure cookers not used			
QC Date, contents, sterilization time, temperature, total cycle time, and analyst's initials recorded for each cycle			
QC Copy of service contract or internal maintenance protocol and maintenance records kept			
QC Maintenance conducted annually at a minimum, with record of most recent service performed available for inspection			
QC Maximum-temperature-registering thermometer or continuous recording device used each autoclave cycle and temperature recorded			
QC Overcrowding avoided			
QC Spore strips or ampules used monthly			
QC Automatic timing mechanism checked quarterly with stopwatch or other accurate timepiece or time signal			
Autoclave door seals clean and free of caramelized media			
Autoclave drain screen cleaned frequently			
3.6 Hot Air Oven			
Maintains stable sterilization temperature of 170-180°C for at least 2 hours			

Element	Yes	No	Comments
Only dry items sterilized in hot air oven			
Overcrowding avoided			
Oven thermometer graduated in 10°C increments or less, with bulb placed in sand during use			
QC Date, contents, sterilization time, temperature, and analyst's initials recorded for each cycle			
QC Spore strip or ampule used monthly			
3.7 Colony Counter			
Colony counter, dark field model, used to count Heterotrophic Plate Count colonies			
3.8 Conductivity Meter			
Suitable for checking laboratory reagent-grade water, readable in micromhos/cm or microsiemens/cm with measurement error not exceeding 1% or 1 micromhos/cm, whichever is more lenient			
QC Cell constant determined monthly			
In-line unit which cannot be calibrated not used to check reagent-grade water			
3.9 Refrigerator			
Maintains 1-5°C			
Thermometer graduated in 1°C increments or less, with thermometer bulb immersed in liquid			
QC Temperature recorded for days in use at least once per day			
3.10 Inoculating Equipment			
Sterile metal or disposable plastic loops, wood applicator sticks, sterile swabs, or sterile plastic disposable pipet tips used			
Wood applicator sticks sterilized by dry heat			
Metal inoculating loops and needles made of nickel alloy or platinum (nickel alloy loops not used for oxidase test)			
3.11 Membrane Filtration (MF) Equipment			
MF units of stainless steel, glass, or autoclavable plastic, not scratched or corroded and do not leak			

Element	Yes	No	Comments
QC Graduations on funnels used to measure sample volume checked for accuracy have tolerance of ≤2.5%, and a record of this calibration check retained			
10x to 15x stereo microscope with fluorescent light source used to count sheen colonies			
Membrane filters approved by manufacturer for use in total coliform analysis of water			
Membrane filters of cellulose ester, white, gridmarked, 47 mm diameter, and 0.45 µm pore size			
Membrane filters and pads purchased presterilized or autoclaved before use			
Lot number and date received recorded for membrane filters			
3.12 Culture Dishes (loose or tight lids)			
Presterilized plastic or sterilizable glass culture dishes used			
Sterility of glass culture dishes maintained by placement in stainless steel or aluminum canisters or wrapped in heavy aluminum foil or char-resistant paper			
Loose-lid dishes incubated in tight-fitting container with moistened paper towel			
Opened packs of disposable culture dishes resealed between use periods			
3.13 Pipets			
Glass pipets sterilized and maintained in stainless steel or aluminum canisters or wrapped individually in char-resistant paper or aluminum foil			
Pipets with legible markings, not chipped or etched			
Opened packs of disposable sterile pipets resealed between use periods			
Pipets delivering volumes of 10 mL or less accurate within 2.5% tolerance			
Micropipetters used with sterile tips,calibrated annually, and replaced if tolerance greater than 2.5%			
3.14 Culture Tubes and Closures			
Tubes of borosilicate glass or other corrosion-resistant glass or plastic			

Element	Yes	No	Comments
Culture tubes and containers of sufficient size to contain medium plus sample without being more than three quarters full			
Tube closures used of stainless steel, plastic, aluminum, or screw caps with non-toxic liner; cotton plugs not used			
3.15 Sample Containers			
Wide-mouth plastic or non-corrosive glass bottles, with non-leaking ground glass stoppers or caps with non-toxic liners, or sterile plastic bags containing sodium thiosulfate used			
Sample container capacity at least 120 mL (4 oz)			
Glass stoppers covered with aluminum foil or char-resistant paper for sterilization			
Sample containers sterilized by autoclaving or (for glass bottles) dry heat			
Containers moistened with several drops of water before autoclaving to prevent "air lock" sterilization failure			
Sufficient sodium thiosulfate added to sample containers before sterilization, if laboratory analyzes chlorinated water			
3.16 Glassware and Plasticware			
Glassware made of borosilicate glass or other corrosion-resistant glass, free of chips and cracks, with markings legible			
Plastic items clear and non-toxic to microorganisms			
QC Graduated cylinders and pre-calibrated containers used to measure samples volumes accurate with a tolerance of 2.5% or less			
QC New lots of pre-calibrated containers validated to have 2.5% tolerance			
3.17 Ultraviolet Lamp (if used)			
Unit cleaned monthly by wiping with soft cloth moistened with ethanol			
QC If used for sanitization, tested quarterly with UV light meter or by agar spread plate method (other methods acceptable if data demonstrates they are as effective)			
4. GENERAL LABORATORY PRACTICES			
Laboratory facilities clean, temperature and humidity controlled, and adequate lighting			
4.1 Sterilization Procedures			

Element	Yes	No	Comments
Required times for autoclaving material at 121°C (except for membrane filters and pads and carbohydrate-containing media, indicated times represent minimum times, dependent upon volumes, containers, and loads): - membrane filters and pads 10 min - carbohydrate containing media 12-15 min - contaminated test materials 30 min - membrane filter assemblies 15 min - sample collection containers 15 min - individual glassware 15 min - dilution water blank 15 min - rinse water (0.5 - 1 L) 15-30 min* * time depends upon water volume per container and autoclave load			
Autoclaved membrane filters and pads and all media removed immediately after completion of sterilization cycle			
Membrane filter equipment autoclaved before beginning of first filtration series (filtration series ends when 30 minutes or longer elapses after a sample filtered)			
When UV light (254 nm) used to sanitize equipment, all supplies presterilized and QC checks conducted on UV lamp			
UV light used to control bacterial carry-over between samples during filtration series (optional)			
4.2 Sample Containers			
QC Sterility of each lot of sample containers or bags confirmed by adding 25 mL of a sterile non-selective broth to at least one container, incubating at 35 ± 0.5°C for 24 hours and checking for growth			
4.3 Reagent-Grade Water			
Only satisfactorily tested reagent water from stills or deionization units used to prepare media, reagents and dilution/rinse water			

Element			Yes	No	Comments
QC Quality of reagent water should be tested and meets the following criteria: - conductivity - Pb, Cd, Cr Cu, Ni, Zn - total chlorine residual* - heterotrophic plate count* - bacteriological quality of reagent water* *See section 4.3.2 of this chapter for additional details	<2 micromhos/cm (microsiemens/cm) at 25°C not greater than 0.05 mg/L per contaminant, and no greater than 0.1 mg/L total <0.1 mg/L <500/mL ratio of growth rate 0.8:3.0	monthly annually monthly monthly annually			
4.4 Dilution/Rinse Water					
Stock buffer solution or peptone water prepared as specified in Standard Methods					
Stock buffers autoclaved or filter-sterilized and containers labeled, dated, and refrigerated					
Stored stock buffer free of turbidity					
QC Each batch of dilution/rinse water checked for sterility by adding 50 mL of water to 50 mL double strength non-selective broth, incubating at 35 ± 0.5^{0}C for 24 hours, and checking for growth					
4.5 Glassware Washing					
Distilled or deionized water used for final rinse					
QC Glassware inhibitory residue test performed on initial use of washing compound and whenever different formulation or washing procedure used					
QC Batches of dry glassware spot-checked for pH reaction					
Laboratory glassware washed with detergent designed for laboratory use					
5. ANALYTICAL METHODOLOGY					

Element	Yes	No	Comments
5.1 General			
Only analytical methodology specified in Total Coliform Rule and Surface Water Treatment Rule used for compliance samples			
Laboratory certified for all analytical methods it uses for compliance purposes			
Laboratory certified for at least one total coliform method and one fecal coliform or *E. coli* method			
Laboratory certified for a second total coliform method, if one method cannot be used for some drinking waters			
Laboratory that enumerates heterotrophic bacteria (i.e., HPC) for compliance with the Surface Water Treatment Rule certified for the Pour Plate Method			
Absorbent pads, when used, saturated with liquid medium and excess removed			
Water sample shaken vigorously (about 25 times) before analysis			
QC If no total coliform-positive results occur during a quarter, laboratory performs coliform procedure using a known coliform-positive, fecal coliform- and/or *E. coli*-positive control to spike the sample			
Sample volume analyzed for total coliforms in drinking water is 100 ± 2.5 mL			
Media			
Dehydrated or prepared media manufactured commercially used (strongly recommended)			
Dehydrated media stored in cool dry location and caked or discolored dehydrated media discarded			
QC Laboratory media preparation records include: - date of preparation - type of medium - lot number - sterilization time and temperature - final pH - technician's initials			

Element	Yes	No	Comments
QC For liquid media prepared commercially, the following are recorded: - date received - type of medium - lot number - pH verification			
QC Liquid media prepared commercially discarded by manufacturer's expiration date			
QC Each new lot of dehydrated and prepared commercial medium checked before use with positive and negative culture controls and results recorded			
QC Each new batch of laboratory-prepared medium checked before use with positive and negative culture controls and results recorded			
Prepared plates refrigerated in sealed plastic bags or containers not longer than two weeks, with bag or container dated with preparation or expiration date			
Loose-cap tubes of broth stored at <30°C no longer than two weeks, tightly capped tubes no longer than 3 months at <30°C			
Refrigerated medium incubated at room temperature overnight before use and discarded if growth observed			
QC Parallel testing performed between a newly approved test procedure and another EPA-approved procedure for several months and/or several seasons (recommended)			
5.2 Membrane Filter (MF) Technique (for total coliforms in drinking water)			
Media			
M-Endo broth or agar or LES Endo agar in single step or enrichment technique used			
Ethanol not denatured			
Medium prepared in sterile flask and dissolved using boiling water bath or hot plate with stir bar			
Medium not boiled			
LES Endo agar medium pH 7.2 ± 0.2 M-Endo medium pH 7.2 ± 0.1			
MF broth refrigerated no longer than 96 hours, poured MF agar plates no longer than 2 weeks, ampuled M-Endo broth as per manufacturer's expiration date			

Element	Yes	No	Comments
Uninoculated media discarded if growth or surface sheen observed			
QC Sterility check conducted on each funnel in use at beginning and end of each filtration series (filtration series ends when 30 minutes or more elapse between sample filtrations)			
QC If sterility control indicates contamination, all data rejected and another sample requested			
Funnels rinsed with two or three 20-30 mL portions of sterile rinse water after each sample filtration to prevent carry-over			
Inoculated medium incubated at 35° ± 0.5°C for 22-24 hours			
Samples resulting in confluent or too numerous to count (TNTC) growth invalidated unless total coliforms detected (if laboratory performs verification test before invalidation and test is total coliform-positive, sample is reported as such, but if test is total coliform-negative, sample is invalidated)			
Sample not invalidated if membrane filter contains at least one sheen colony			
All sheen colonies verified (up to a maximum of five) using either single strength (LB) or (LTB) and single strength (BGLBB) or an EPA-approved cytochrome oxidase and beta-galactosidase rapid test procedure			
When picking individual colonies, up to five red questionable sheen colonies and/or red non-sheen colonies verified to include different types or entire MF surface is swabbed			
When EC medium or EC medium + MUG used, colonies transferred by employing one option specified by 141.21 (f)(5)			
Swab used to transfer presumptive total coliform-positive culture can inoculate up to three different media (e.g., EC medium, LTB, and BGLBB in that order)			
5.3 Multiple Tube Fermentation Technique (MTF or MPN) (for total coliforms in drinking water)			
Total sample volume of 100 mL examined by test configuration found in 141.21 (f)(3) or Appendix G			
Media			
LTB used in presumptive test and BGLBB in confirmed test			

Element	Yes	No	Comments
LB used if system conducts at least 25 parallel tests between this medium and LTB and demonstrates false-positive rate and false-negative rate for total coliforms of less than 10%, with comparison documented and records retained			
LTB pH 6.8 ± 0.2			
BGLBB pH 7.2 ± 0.2			
Test medium concentration adjusted to compensate for sample volume so resulting medium single strength after sample addition			
If single 100 mL sample volume used, inverted vial replaced with acid indicator			
Medium autoclaved at 121°C for 12-15 minutes			
Inverted vials in sterile medium free of bubbles and at least one-half to two-thirds covered after water sample added			
Refrigerated sterile MTF media incubated overnight at room temperature before use, with tubes/bottles showing growth and/or bubbles discarded			
Prepared broth media stored in dark at <30°C for no longer than 3 months in screw-cap tubes/bottles, two weeks for those with loose-fitting closures			
Media discarded if evaporation exceeds 10% of original volume			
Inoculated medium incubated at 35°C ± 0.5°C for 24 ± 2 hours			
If no gas or acid detected, inoculated medium incubated for another 24 hours			
All samples showing turbid culture (i.e., heavy growth, opaque) in the absence of gas/acid production invalidated and another sample collected from the same location (if laboratory performs confirmed test on turbid culture and confirmed test is total coliform-positive, sample reported as such, but if total coliform-negative, sample is invalidated)			
All 24- and 48-hour gas-positive or acid-positive tubes confirmed using BGLBB			
Completed Test not required			
When MTF test used on water supplies that have a history of confluent growth or TNTC by the MF procedure, all presumptive tubes with heavy growth without gas/acid production submitted to confirmed test and fecal coliform/*E. coli* test to check for coliform suppression			

Element	Yes	No	Comments
5.4 Presence-Absence (P-A) Coliform Test (for drinking water)			
Medium			
When six-times formulation strength medium used, medium filter-sterilized, not autoclaved			
Medium autoclaved for 12 minutes at 121°C with total time in autoclave less than 30 minutes and with space between bottles			
Medium pH 6.8 ± 0.2			
Prepared medium stored in the dark at <30°C for no longer than 3 months			
Stored medium discarded if evaporation exceeds 10% of original volume			
100 mL sample inoculated into P-A culture bottle			
Medium incubated at 35° ± 0.5°C and observed for yellow color (acid) after 24 and 48 hours			
Yellow cultures confirmed in BGLBB and fecal coliform/*E. coli* test conducted			
Non-yellow turbid culture in P-A medium invalidated and another sample obtained from the same location (if confirmed test performed and sample is total coliform-positive, sample is reported as such, but if confirmed test is negative, sample invalidated)			
5.5 Fecal Coliform Test (using EC Medium for fecal coliforms in drinking or source water, or A-1 Medium for fecal coliforms in source water only)			
EC medium used to determine whether total coliform-positive culture taken from distribution system contains fecal coliforms, in accordance with Total Coliform Rule			
EC medium used to enumerate fecal coliforms in source water, in accordance with Surface Water Treatment Rule, using cultures transferred from each total coliform-positive tube			
Three sample volumes (10, 1, and 0.1 mL) and 5 or 10 tubes/sample volume used			
Autoclaved at 121°C for 12-15 minutes			
Medium pH 6.9 ± 0.2			
Inverted vials free of bubbles and at least one-half to two-thirds covered after sample added			

Element	Yes	No	Comments
Tubes with loose-fitting closures used within two weeks, tightly closed screw-cap tubes no longer than 3 months when held in the dark at <30°C			
Refrigerated medium incubated at room temperature overnight before use and tubes with growth or bubbles in vials discarded			
Alternatively, A-1 Medium used to enumerate fecal coliforms in source water, in accordance with Surface Water Treatment Rule			
A-1 medium not used for drinking water samples			
Three sample volumes of source water (10, 1, and 0.1 mL) and 5 or 10 tubes/sample volume used			
Autoclaved at 121°C for 10 minutes			
Medium pH 6.9 ± 0.1			
Inverted vials free of air bubbles and at least one-half to two-thirds covered after water sample added			
Loose-cap tubes stored in dark at room temperature no longer than 2 weeks, tightly closed screw-cap tubes no longer than 3 months when held in the dark at <30°C			
Water level in water bath above upper level of medium in culture tubes			
EC Medium incubated at 44.5°C ± 0.2°C for 24 ± 2 hours			
A-1 Medium incubated at 35°C ± 0.5°C for 3 hours, then at 44.5°C ± 0.2°C for 21 ± 2 hours			
Any gas detected in inverted vial considered fecal coliform positive			
5.6 Chromogenic/Fluorogenic Substrate Tests (MMO-MUG Test [Colilert] for total coliforms in source water and total coliforms and *E. coli* in drinking water; Colisure Test for total coliforms and *E. coli* in drinking water)			
Media			
Purchased from commercially available source only			
Media protected from light			
Colisure medium refrigerated until use, brought to room temperature before adding sample			
Each lot of medium checked for autofluoresence before use with 366-nm ultraviolet light with 6 watt bulb			

Element	Yes	No	Comments
Medium which exhibits faint fluorescence discarded and another lot used			
Medium plus sample which exhibits color change before incubation discarded and another batch of medium used			
QC Each lot of medium checked by inoculating sterile water containing the medium with a MUG-positive *E. coli* strain, a MUG-negative coliform, and a non-coliform and analyzing them			
If Quanti-Tray or Quanti-Tray 2000 test used with Colilert medium, sealer checked monthly to determine leakage			
Glass bottles that contain inoculated medium checked with 366-nm ultraviolet light source with 6 watt bulb and discarded if fluorescence observed before incubation			
For enumeration of total coliforms in source water with Colilert Test, 5 or 10 tube MTF, Quanti-Tray, or Quanti-Tray 2000 used for each sample dilution tested			
For chromogenic/fluorogenic substrate test only, sterile dechlorinated tap water, deionized water, or distilled water used as dilution water			
For determining presence of total coliforms in drinking water by chromogenic/fluorogenic substrate test, 10 tubes each containing 10 mL water sample or single vessel containing 100 mL sample used			
For Colilert Test:			
Sample incubated at 35° ± 0.5° for 24 hours (for Colilert-18 test, sample incubated 18 hours)			
Yellow color in medium equal to or greater than reference comparator indicates total coliform presence			
Medium with yellow color lighter than comparator and incubated for another 4 hours (28 hours total)			
Yellow color in medium lighter than comparator incubated for 28 hours recorded as negative			
For Colisure Test:			
Sample incubated at 35° ± 0.5°C for 28 to 48 hours			
Total coliform positive sample indicates color change from yellow to magenta			

Element	Yes	No	Comments
For *E. coli* determination, UV lamp (366-nm, 6-watt) shone on total coliform-positive bottles/tubes in darkened room with blue fluorescence indicating *E. coli* presence			
QC Air-type incubators tested to determine time necessary for cold 100 mL water sample (or set of 100 mL water samples) to reach incubation temperature of 35°C, ensuring specified incubation time at that temperature is followed			
Colilert/Colisure Test not used to confirm total coliforms on membrane filters			
Colilert/Colisure Test not used to confirm total coliforms in MTF or P-A tests			
5.7 EC Medium + MUG (for *E. coli*)			
Total coliform-positive culture transferred to EC medium + MUG			
Medium			
MUG added to EC medium before autoclaving or commercially available EC + MUG used			
Final MUG concentration 50 µg/mL			
Medium pH 6.9 ± 0.2			
Inverted vial omitted (optional)			
Test tubes and autoclaved medium checked for autofluorescence before use with 366-nm UV light			
If fluorescence exhibited, non-fluorescing tubes or another lot of medium that does not fluoresce used or MUG-positive (*E. coli*) and a MUG-negative (e.g. uninoculated) control included for each analysis			
Prepared medium in tubes with loose-fitting closures used within two weeks, or three months for tightly closed screw-cap tubes when held in the dark at <30°C			
Uninoculated medium with growth discarded			
QC Each lot of commercially prepared medium and each batch of laboratory-prepared medium checked by inoculating LTB with positive and negative culture controls, incubating at 35°C ± 0.5°C for 24 hours and then transferring to EC Medium + MUG for further incubation at 44.5°C ± 0.2°C for 24 hours, with results read and recorded			
Water level of water bath above upper level of medium			

Element	Yes	No	Comments
Incubated at 44.5° ± 0.2°C for 24 ± 2 hours			
Fluorescence checked using UV lamp (366-nm) with 6 watt bulb in a darkened room			
5.8 Nutrient Agar + MUG Test (for *E. coli*)			
Medium			
Medium autoclaved in 100 mL volumes at 121°C for 15 minutes			
MUG added to Nutrient Agar before autoclaving or Nutrient Agar + MUG purchased commercially			
Final MUG concentration 100 µg/L			
Medium pH 6.8 ± 0.2			
Medium in petri dishes stored refrigerated in plastic bag or tightly closed container and used within two weeks			
Refrigerated sterilized medium incubated at room temperature overnight and plates with growth discarded			
QC Quality of medium lot/batch evaluated by filtering or spot-inoculating positive and negative control cultures onto membrane filter on M-Endo medium, incubating at 35°C for 24 hours, then transferring filter to NA + MUG and further incubating at 35°C for 4 hours, with results read and recorded			
Filter containing total coliform colony(ies) transferred to surface of Nutrient Agar + MUG medium			
Before incubation, presence of each sheen colony marked on petri dish lid with permanent marker, and lid and base marked to realign lid when removed			
For total coliform verification test, portion of colony transferred with needle before or after NA + MUG incubation			
Alternatively, membrane filter surface swabbed with sterile cotton swab after 4 hour incubation and transferred to total coliform verification test			
Inoculated medium incubated at 35 ± 0.5°C for 4 hours			
Fluorescence checked using UV lamp (366 nm) with 6 watt bulb in a darkened room, with any fluorescence in halo around sheen colony considered positive for *E. coli*			
5.9 Heterotrophic Plate Count for enumerating heterotrophs in drinking water			

Element	Yes	No	Comments
Pour Plate Method used for enumerating heterotrophic bacteria in drinking water and for testing reagent grade water			
For systems granted a variance from Total Coliform Rule's maximum contaminant level, any method in Standard Methods used with R2A medium for enumerating heterotrophic bacteria in drinking water			
Media (plate count agar [tryptone glucose extract agar] and R2A agar)			
Plate count agar pH 7.0 ± 0.2			
R2A agar pH 7.2 ± 0.2			
(For Pour Plate Method) melted agar tempered at 44-46°C in waterbath before pouring, held no longer than 3 hours, and melted only once			
(For Spread Plate Method) 15 mL of R2A medium or other medium poured into petri dish and solidified			
Refrigerated medium in bottles or screw-capped tubes stored for up to 6 months, petri dishes with medium for up to 2 weeks (one week for R2A prepared petri dishes)			
Countable plates obtained for most potable waters by plating 1.0 mL and/or 0.1 mL volume of undiluted sample			
At least duplicate plates per dilution used			
(For Pour Plate Method)			
Sample pipetted aseptically into bottom of petri dish and then 12-15 mL tempered melted agar added			
Sample mixed with spillage avoided			
After solidification on level surface, plates inverted and incubated at 35°C ± 0.5°C for 48 ± 3 hours			
Plates stacked no more than four high			
(For Spread Plate Method)			
0.1 or 0.5 mL of sample or dilution pipetted onto surface of pre-dried agar plate and inoculum spread over entire agar surface using sterile bent glass rod			
Inoculum absorbed completely before plates inverted and incubated at 20-28°C for 5-7 days			
(For Membrane Filter Technique)			

Element	Yes	No	Comments
Volume filtered to yield between 20-200 colonies			
Filter transferred to petri dish containing 5 mL solidified R2A medium and incubated at 20-28°C for 5-7 days			
Petri dishes with loose-fitting lids placed in container with close fitting lid and moistened paper towels			
Colonies counted using stereoscopic microscope at 10-15X magnification			
(For Pour Plate and Spread Plate Techniques)			
Colonies counted manually using dark field colony counter			
Only plates with 30 to 300 colonies counted, except for plates inoculated with 1.0 mL of undiluted sample			
Fully automatic colony counters not used			
QC Medium sterility verified by pouring final control plate and data rejected if control contaminated			
5.10 Membrane Filter Technique (for enumerating total coliforms in source water)			
Same as Section 5.2, Membrane Filter Technique (for total coliforms in drinking water), except invalidation does not apply			
Appropriate sample dilutions used to yield 20 to 80 total coliform colonies per membrane			
Initial counts adjusted based upon verified data			
QC If two or more analysts available, each counts total coliform colonies on same membrane monthly and agree within 10%			
5.11 Multiple Tube Fermentation Technique (for enumerating total coliforms in source water)			
At least three series of 5 tubes each with appropriate sample dilutions of source water used			
Same as Section 5.3, Multiple Tube Fermentation Technique (for total coliforms in drinking water) except on sample invalidation			
All samples invalidated which produce turbid growth in the absence of gas/acid production in LTB or LB and another sample obtained, which may be tested using another method			

Element	Yes	No	Comments
Alternatively, confirmed test performed on turbid culture in the absence of gas/acid production and, if total coliform-positive, most probable number reported, or if total coliform-negative, sample invalidated and another requested			
5.12 Fecal Coliform Membrane Filter Procedure (for enumerating fecal coliforms in source water)			
Medium			
m-FC broth (with or without agar) sterilized by bringing to boiling point, not autoclaved			
Medium final pH 7.4 ± 0.2			
Prepared medium refrigerated and broth discarded after 96 hours, poured agar medium in petri dishes after 2 weeks			
Uninoculated medium discarded if growth observed			
Sample volumes yield 20-60 fecal coliform colonies per membrane for at least one dilution			
QC Funnels rinsed with two or three 20-30 mL portions of sterile rinse water after each sample filtration to prevent carry-over			
QC Sterility checked at beginning and end of each filtration series and all data rejected from affected samples and resampling requested if controls contaminated			
Inoculated medium incubated at 44.5°C ± 0.2°C for 24 ± 2 hours			
QC If two or more analysts available, each counts fecal coliform colonies on same membrane monthly and counts agree within 10%			
6. SAMPLE COLLECTION, HANDLING, AND PRESERVATION			
6.1 Sample Collector			
Trained in aseptic sampling procedures and, if required, approved by appropriate regulatory authority or designated representative			
6.2 Sampling			
Sample representative of water distribution system			
Water taps used for sampling free of aerators, strainers, hose attachments, mixing type faucets, and purification devices			
Cold water tap used			
Service line cleared before sampling by maintaining steady water flow for at least 2 minutes			

Element	Yes	No	Comments
At least 100 mL sample volume collected, allowing one inch air space in container			
Sample information form completed immediately after sample collection			
Source water representative of supply, collected not too far intake at a reasonable distance from shore			
6.3 Sample Icing			
Samples held at <10°C during transit to laboratory (recommended for drinking water, required for source water)			
6.4 Sample Holding/Travel Time			
Time from sample collection to initiation of analysis for total coliforms, fecal coliforms, or *E. coli* does not exceed 30 hours for drinking water samples			
Time from sample collection to initiation of analysis for total coliforms and fecal coliforms in source water and heterotrophic bacteria in drinking water does not exceed 8 hours			
All samples analyzed on day of receipt by laboratory, unless laboratory receives sample late in day and then refrigerates sample overnight and begins analysis within holding time			
6.5 Sample Information Form			
Entered on sample information form in indelible ink: - name of system (PWSS identification number if available) - sample identification (if any) - sample site location - sample type (e.g. routine, repeat, raw or process) - date and time of collection - analysis required - disinfectant residual - name of sampler and organization (if not water system) - sampler's initials - person(s) transporting sample from system to laboratory (if not sampler) - transportation condition (e.g. <10°C, protection from sunlight), if shipper used, shipping records available - any remarks			
6.6 Chain-of-Custody			
Applicable regulations followed by collectors and laboratory			
7. QUALITY ASSURANCE			

Element	Yes	No	Comments
Written QA Plan prepared, followed, and available for inspection			
8. RECORDS AND DATA REPORTING			
8.1 Legal Defensibility			
Compliance monitoring data legally defensible by keeping thorough and accurate records			
QA plan and/or SOPs describe policies and procedures used by facility for record retention and storage			
Chain-of-custody procedures used if samples expected to become part of legal action			
8.2 Maintenance of Records			
Microbiological analyses records kept by or accessible to laboratory for at least 5 years or until next certification data audit completed, whichever is longer			
Client water system notified before disposal of records			
8.3 Sampling Records			
Data recorded in ink with changes lined through such that original entry visible and changes initialed and dated			
Sampling records include: - sample information form, from Section 6.5 - date and time of sample receipt by laboratory - name of laboratory person receiving sample - if any deficiency in sample condition noted, sample, at a minimum, flagged - if sample transit time exceeds 30 hours (8 hours for source water samples), sample tagged			
8.4 Analytical Records			
Data recorded in ink with changes lined through such that original entry visible and with changes initialed and dated			
Analytical records include: - laboratory sample identification - date and time analysis begins - laboratory and person(s) responsible for performing analysis - analytical technique or method used - all items marked QC - results of analysis			
8.5 Preventive Maintenance			

Element	Yes	No	Comments
Preventive maintenance and repair records for all instruments and equipment kept for 5 years			
9. ACTION RESPONSE TO LABORATORY RESULTS			
9.1 Testing Total Coliform-Positive Cultures			
For the Total Coliform Rule, all total coliform positive cultures tested for presence of either fecal coliforms or *E. coli*			
9.2 Notification of Positive Results			
For Total Coliform Rule, proper authority notified promptly by laboratory of positive total coliform, fecal coliform or *E. coli* results			
Total coliform positive result based on confirmed phase for MTF Technique and P-A Coliform Test or verified test for MF Technique (no requirement for confirmation of positive Colilert/Colisure, fecal coliform or *E. coli* tests)			
9.3 Invalidation of Total Coliform-Negative Sample			
For Total Coliform Rule, proper authority notified when results indicate non-coliforms may have interfered with total coliform analysis			

Chapter VI
Critical Elements for Radiochemistry

1. Personnel

1.1 Laboratory Supervisor

The laboratory supervisor should have at least a bachelor's degree with a major in chemistry or equivalent and at least one year of experience in the analysis of drinking water for radiochemicals. The laboratory supervisor should have at least a working knowledge of quality assurance principles. The laboratory supervisor has immediate responsibility to insure that all laboratory personnel have demonstrated their ability to satisfactorily perform the analyses to which they are assigned and that all data reported by the laboratory meet the required quality assurance criteria.

1.2 Laboratory Analyst

The laboratory analyst should have at least a bachelor's degree with a major in chemistry or equivalent and at least one year of experience in the analysis of drinking water for radiochemicals. If the analyst is responsible for the operation of analytical instrumentation, he or she should have completed specialized training offered by the manufacturer or another qualified training facility or served a period of apprenticeship under an experienced analyst. The duration of this apprenticeship is proportional to the sophistication of the instrument.

Before beginning the analysis of compliance samples, the analyst should demonstrate acceptable results for blanks, blind spikes, precision, accuracy, method detection and specificity and satisfactory analysis on unknown samples.

1.3 Technician

The laboratory technician should have at least a high school diploma or equivalent, complete a method training program under an experienced analyst and have six months bench experience in the analysis of drinking water samples.

Before beginning the analysis of compliance samples, the technician should demonstrate acceptable results for blanks, blind spikes, precision, accuracy, method detection and specificity and satisfactory analysis on unknown samples.

1.4 Sampling Personnel

Personnel who collect samples should have training in the proper collection technique for all types of samples which they collect. Their technique should be reviewed by experienced sampling personnel.

1.5 Analysts and Operators in Training

Data produced by analysts and instrument operators while in the process of obtaining the required training or experience are acceptable only when reviewed and validated by a fully qualified analyst or the laboratory supervisor.

1.6 Waiver of Academic Training Requirement

The certification officer may waive the need for specified academic training, on a case-by-case basis, for highly experienced analysts.

Training records should be maintained for all personnel. These should include all job related formal training taken by the analyst which pertains to any aspect of his/her responsibilities, including but not limited to analytical methodology, laboratory safety, sampling, quality assurance, data analysis, etc.

2. Laboratory Facilities

2.1 General

The analysis of compliance samples should be conducted in a laboratory where the security and integrity of the samples and the data can be maintained. The laboratory facilities should be clean, have adequate temperature and humidity control and adequate lighting at the bench top. The laboratory must have provisions for the proper disposal of chemical and
radiological wastes, including liquid scintillation cocktail mixtures. The appropriate type of exhaust hoods are required where applicable.

A minimum of 150-200 square feet of laboratory space and 15 linear feet of usable bench space per analyst are recommended. There should be sufficient bench space for processing samples. Workbench space should be convenient to sink, water, gas, vacuum and electrical outlets free from surges.

Analytical and sample storage areas should be isolated from all potential sources of contamination. Any sample having an emission rate in excess of 0.5 mrem/hr should be stored in a secured location away from drinking water samples. There should be sufficient storage space for chemicals, glassware and portable equipment, sufficient floor and bench space for stationary equipment and areas for cleaning materials.

2.2 Instrumentation

Instruments must be properly grounded. Counting instruments must be located in a room other than the one in which samples and standards are being prepared and in which other types of wet chemical analyses are being performed.

An uninterrupted power supply should be available for radiation counting equipment.

2.3 Preparation of Standards

In areas where radioactive standards are being prepared, care should be taken to minimize contamination of surfaces, other samples and personnel. Either bench surfaces of an impervious material covered with adsorbent paper, or plastic or fiberglass trays lined with adsorbent paper are acceptable.

3. Laboratory Equipment and Instrumentation

The laboratory is required to have the equipment, supplies and instrumentation necessary to perform the approved methods for which it is certified.

3.1 Radiation Counting Instruments

The types of radiation counting systems needed to comply with measurements described in theregulations are as follows:

3.1.1 Liquid scintillation system: A liquid scintillation system is essential if the laboratory is to be certified for the measurement of tritium in drinking water samples. It is recommended that the liquid scintillation system have spectral analysis capabilities to establish proper regions of energy discrimination. The system must have a sensitivity adequate to meet or exceed the detection limit requirements of CFR 141.25(c).

3.1.2 Gas-flow proportional counting system: A gas-flow proportional counting system may be used for the measurement of gross alpha and gross beta activities, radium-226, radium-228, strontium-89, strontium-90, radioactive cesium,and iodine-131 as described in the reference in CFR 141.25(a). The detector may be either a "windowless" (internal proportional counter) or a "thin window" type. A combination of shielding and a cosmic (guard) detector operated in anticoincidence with the main detector should be used to achieve low background beta counting capability. The alpha and beta background count of the system must be low enough so that the sensitivity of the radioanalysis of water samples will meet or exceed the requirement of 40 CFR 141.25(c) with reasonable counting time (not more than 1,000 minutes).

3.1.3 Alpha scintillation counting system: For measurement of gross alpha activities and radium-226, a scintillation system designed for alpha counting may be substituted for the gas-flow proportional counter described. In such a system, a Mylar disc coated with a phosphor (silver-activated zinc sulfide) is either placed directly on the sample or on the face of a photomultiplier tube, enclosed within a light-tight container, along with the appropriate electronics (high voltage supply, preamplifier, amplifier, timer and scaler).

3.1.4 Scintillation cell system: A scintillation system designed to accept scintillation flasks ("Lucas cells") should be used for the specific measurement of radium-226 by the radon emanation method. The system consists of a light-tight enclosure capable of accepting the scintillation flasks, a detector (phototube), and the appropriate electronics (high voltage supply, amplifier, timers, and scalers). The flasks (cells) needed for this measurement may either be purchased from commercial suppliers or constructed by the laboratory.

3.1.5 Gamma spectrometer systems: Either a solid state lithium drifted germanium Ge(Li) detector or a high purity intrinsic Ge(Hp) germanium detector connected to a multichannel analyzer is needed if the laboratory is to be certified for analyses of manmade photon emitters.

A system with a lithium drifted germanium, or a high purity intrinsic germanium detector may be used for measurement of manmade photon emitters if the efficiency of the detector is adequate to meet the detection limits required at 40 CFR 141.25(c). These detectors should be shielded with a minimum of 10cm of iron or equivalent. The multichannel analyzer, in addition to appropriate electronics should contain a memory of not less than 4096 channels and at least one readout device.

3.1.6 Alpha Spectrometer System and Beta Scintillation: These counters and others as mentioned in legislation.

4. General Laboratory Practices

4.1 Chemicals/reagents: Chemicals and reagents used must meet the specifications in the methods. If not specified, then "Analytical reagent grade" (AR) or American Chemical Society (ACS) grade chemicals or better should be used. Radioactive standards should be certified by the National Institute of Standards and Technology (NIST, formerly NBS) or traceable to a certified source.

4.2 Reagent Water: The laboratory should have a source of reagent water, ASTM type 1,2,3 or equivalent, having a minimum resistance of 10 megohms/cm at 25°C. The background radioactivity should be checked periodically and should not be at a level which interfers with the radionuclide tests.

4.3 Glassware/Plasticware: Specific requirements in the methods for the cleaning of glassware must be followed. If there are no specifications, glassware should be acid washed then washed in detergent solution and thoroughly rinsed first with tap water and then with reagent water.

4.4 Safety: Guidelines in the Laboratory Safety Manual, the Chemical Hygiene Plan or the Standard Operating Procedures should include proper worker safety training and protection. When circumstances warrant the use of protective equipment, this should include the use of gloves, laboratory coats, eye protection, and the proper pipetting techniques.

5. Analytical Methods

The approved methods cited in the CFR at §141.25(a) and (b) must be used for the analysis of drinking water compliance samples. These are listed in Table VI-1.

6. Sample Collection, Handling, and Preservation

Sample containers, preservatives and holding times in the methods must be followed. Table VI-2 lists critical elements for sample handling including preservation. Sample preservatives should be checked for radioactive content.

7. Quality Assurance

Additional information is contained in Appendix H. Specific items are referenced throughout.

7.1 General Requirements

7.1.1 Availability of Records and Documents: The analytical methods, quality assurance manual and standard operating procedures should be readily available to the analysts. All quality control data and records should be available for inspection by the certification officer.

7.2 Performance Evaluation Studies Two types of performance evaluation studies are administered by NERL-LV:

7.2.1 Blind performance evaluation studies: Two water samples (A&B) are distributed twice each year. These samples contain a mixture of alpha, beta, and gamma analytes. A laboratory must successfully analyze at least one set of performance samples each year (either those distributed by NERL-LV or other PE samples

acceptable to the State) within the acceptance limits for each analyte for which the laboratory wishes to be certified.

7.2.2 Other performance evaluation samples: Water samples containing a varied number of analytes are distributed several times per year. A laboratory should successfully analyze at least two sets each year within the acceptance limits in the regulations for each analyte for which the laboratory wishes to be certified.

7.2.3 Acceptance Limits: The radionuclide performance evaluation studies and their acceptance limits are described in the draft document, *Environmental Radioactivity Performance Evaluation Studies Program and Radioactive Standards Distribution Program* (EPA 600/4-81-004 and EPA 600/4-80-044), available from NERL-LV.

7.3 Operating Manuals

Operating manuals and calibration protocols for counting instruments should be available to analysts and technicians.

7.4 Maintenance of Records

Calibration data and maintenance records on all radiation instruments and analytical balances should be maintained in a permanent record.

7.5 Quality Control Requirements

The following are required for each analyte for which the laboratory is certified:

7.5.1 Duplicates: A minimum of one sample for every 10 or fewer compliance samples must be analyzed in duplicate to verify internal laboratory precision for each method. The relative percent difference between duplicates should be less than or equal to two sigma counting error for the pair of samples. If the difference exceeds the two sigma counting error or 10% of the measured concentration, whichever is greater, prior measurements are suspect; calculations and procedures should be examined and samples should be recounted. All compliance samples, along with the duplicate analyses should be discarded if reanalysis of these samples exceeds the prescribed limits for duplicate analyses or if they cannot be recounted.

7.5.2 Fortified Sample Matrix Matrix spikes are prepared by adding a known quantity of traceable standard (if available) solution to an actual sample. They are prepared with the sample batch and processed identically to the actual samples. The added concentration should not be less than the background. A matrix spike sample must be prepared and used for each batch of samples, regardless of batch size. Agreement of the measured value +/- 20% (95% CL) of the expected value indicates validity of the calibration curve. If the percent recovery exceeds this limit, the result should be flagged as suspect due to matrix interference. Over time, an effort should be made to spike samples from all the matrixes analyzed.

7.5.3 Counting and Background Check A counting standard and a background sample should be measured with each set of 20 or fewer samples processed in a day.

7.5.4 Composited Samples Samples may be composited by the utility or the laboratory provided that sample aliquots are filtered before preservation and preservative is added to the first and subsequent sample aliquots. Generally, it is preferred to have the laboratory composite the samples to insure integrity over time. Analysis of composited samples should be completed within one year after the first sample or within 30 days of the last sample if the time between samples was less than 90 days.

7.6 Instrument Performance Charts/Records

Quality control performance charts or records should be maintained for each instrument.

7.7 QA Plan
The laboratory should prepare and follow a written QA plan (see Chapter III).

8. Records and Data Reporting

8.1 Legal Defensibility: Compliance monitoring data should be made legally defensible by keeping thorough and accurate records. The QA plan and/or SOPs should describe the policies and procedures used by the facility for record retention and storage. If samples are expected to become part of a legal action, chain of custody procedures should be used (See Appendix A).

8.2 Maintenance of Records: Public Water Systems are required to maintain records of radionuclide analyses of compliance samples for 10 years (40 CFR 141.33). The laboratory should maintain easily accessible records for five years or until the next certification data audit is complete, whichever is longer. The client water system should be notified before disposing of records so they may request copies if needed. This includes all raw data, calculations, and quality control data. These data files may be either hard copy, microfiche or electronic. Electronic data should always be backed up by protected tape or disk or hard copy. If the laboratory changes its computer hardware or software, it should make provisions for transferring old data to the new system so that it remains retrievable within the time frames specified above. Data which is expected to become part of a legal action will probably need to be maintained for a longer period of time. Check with your legal counsel. See Appendix H, section 3.0, and *Good Automated Laboratory Practices*, EPA 2185, Office of Information Management, Research Triangle Park, NC 27711, 8/10/95.

8.3 Sampling Records: Data should be recorded in ink with any changes lined through such that original entry is visible. Changes should be initialed and dated. The following information should be readily available in a summary or other record(s):

8.3.1 Date, location (including name of utility and PWSS ID #), site within the system, time of sampling, name, organization and phone number of the sampler, and analyses required;

8.3.2 Identification of the sample as to whether it is a routine distribution system sample, check sample, raw or finished water sample, repeat or confirmation sample or other special purpose sample;

8.3.3 Date of receipt of the sample;

8.3.4 Sample volume/weight, container type, preservation and holding time and condition on receipt;

8.3.5 pH and disinfectant residual at time of sampling (from plant records);

8.3.6 Transportation and delivery of the sample (person/carrier, conditions).

8.4 Analytical Records Data should be recorded in ink with any changes lined through such that original entry is visible. Changes should be initialed and dated. The following information should be readily available:

8.4.1 Laboratory and persons responsible for performing analysis;

8.4.2 Analytical techniques/methods used;

8.4.3 Date and time of analysis;

8.4.4 Results of sample and quality control analyses;

8.4.5 Calibration and standards information;

8.4.6 Counting and detection limit data;

8.4.7 Results of analyses.

8.6 Computer programs: Computer programs should be verified initially and periodically by manual calculations and the calculations should be available for inspection. Access to computer programs and electronic data should be limited to appropriate personnel.

9. Action Response to Laboratory Results

When a laboratory is responsible, either by contract or state policy, to report sample results which would cause a system to be out of compliance, the proper authority should be promptly notified and a request should be made for resampling from the same sampling point immediately. See Chapter III.

Table VI-1 Methods for Radionuclide Analysis CFR 141.25 (as of 2/1997)

Contaminant	Methodology	Reference (method or page number)								
		EPA[1]	EPA[2]	EPA[3]	EPA[4]	SM[5]	ASTM[6]	USGS[7]	DOE[8]	Other
Naturally occurring										
Gross alpha[11] and beta	Evaporation	900.0	p 1	00-01	p 1	302, 7110 B	. . . . .	R-1120-76	. . . . .	
Gross alpha[11]	Co-precipitation	. . . . .	. . . . .	00-02	. . . . .	7110 C	. . . . .	. . . . .	. . . . .	
Radium 226	Radon emanation, Radiochemical	903.1 903.0	p 16 p 13	Ra-04 Ra-03	p 19	7500-Ra C 304, 305, 7500-Ra B	D 3454-91 D 2460-90	R-1141-76 R-1140-76	Ra-05	N.Y.[9]
Radium 228	Radiochemical	904.0	p 24	Ra-05	p 19	304, 7500-Ra D	. . . . .	R-1142-76	. . . . .	N.Y.[9] N. J.[10]
Uranium[12]	Radiochemical Fluorometric Alpha spectrometry Laser Phosphorimetry	908.0 908.1	. . . .	. . . . 00-07	. . . . p 33	7500-U B 7500-U C (17th Ed.) 7500-U C (18th or 19th Ed.)	. . . . . . D 2907-91 D 3972-90 D 5174-91	. . . . . . R-1180-76 R-1181-76 R-1182-76	. . . . . . U-04 U-02	
Man-made										
Radioactive cesium	Radiochemical Gamma ray spectrometry	901.0 901.1	p 4	. . . .	. . . . . . p 92	7500-Cs B 7120 (19th Ed.)	D-2459-72 D 3649-91	R-1111-76 R-1110-76	. . . . . . 4.5.2.3	
Radioactive iodine	Radiochemical Gamma ray spectrometry	902.0 901.1	p 6 p 9	. . . .	. . . . . . p 92	7500-I B 7500-I C 7500-I D 7120 (19th Ed.)	 D 3649-91 D 4785-88	. . . .	. . . . . . 4.5.2.3	
Radioactive Strontium 89, 90	Radiochemical	905.0	p 29	Sr-04	p. 65	303, 7500-Sr B	. . . . .	R-1160-76	Sr-01 Sr-02	
Tritium	Liquid scintillation	906.0	p 34	H-02	p. 87	306, 7500-3H B	D 4107-91	R-1171-76	. . . . .	
Gamma emitters	Gamma ray Spectrometry	901.1 902.0 901.0	. . . . .	. . . . .	p 92	7120 (19th Ed.) 7500-Cs B 7500-I B	D 3649-91 D 4785-88	R-1110-76	4.5.2.3	

The procedures shall be done in accordance with the documents listed below. The incorporation by reference of the following documents was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the documents may be obtained from the sources listed below. Information regarding obtaining these documents can be obtained from the Safe Drinking Water Hotline at 800-426-4791. Documents may be inspected at EPA's Drinking Water Docket, 401 M Street, SW., Washington, DC 20460 (Telephone: 202-260-3027); or at the Office of Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

1. "Prescribed Procedures for Measurement of Radioactivity in Drinking Water", EPA 600/4-80-032 , August 1980. Available at U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (Telephone 800-553-6847) , PB 80-224744.
2. "Interim Radiochemical Methodology for Drinking Water", EPA 600/4-75-008(revised), March 1976. Available at NTIS, ibid. PB 253258.
3. "Radiochemistry Procedures Manual", EPA 520/5-84-006, December 1987. Available at NTIS, ibid. PB 84-215581.
4. "Radiochemical Analytical Procedures for Analysis of Environmental Samples", March 1979. Available at NTIS, ibid. EMSL LV 053917.
5. "Standard Methods for the Examination of Water and Wastewater", 13th, 17th, 18th, 19th Editions, 1971, 1989, 1992, 1995. Available at American Public Health Association, 1015 Fifteenth Street N.W., Washington, D.C. 20005 . All methods are in the 17th, 18th and 19th editions except 7500-U C Fluorometric Uranium was discontinued after the 17th Edition, 7120 Gamma Emitters is only in the 19th Edition, and 302, 303, 304, 305 and 306 are only in the 13th Edition.
6. Annual Book of ASTM Standards, Vol. 11.02, 1994. Available at American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428.
7. "Methods for Determination of Radioactive Substances in Water and Fluvial Sediments", Chapter A5 in Book 5 of Techniques of Water-Resources Investigations of the United States Geological Survey, 1977. Available at U.S. Geological Survey (USGS) Information Services, Box 25286, Federal Center, Denver, CO 80225-0425.
8. "EML Procedures Manual", 27th Edition, Volume 1, 1990. Available at the Environmental Measurements Laboratory, U.S. Department of Energy (DOE), 376 Hudson Street, New York, NY 10014-3621.
9. "Determination of Ra-226 and Ra-228 (Ra-02)", January 1980, Revised June 1982. Available at Radiological Sciences Institute Center for Laboratories and Research, New York State Department of Health, Empire State Plaza, Albany, NY 12201.
10. "Determination of Radium 228 in Drinking Water", August 1980. Available at State of New Jersey, Department of Environmental Protection, Division of Environmental Quality, Bureau of Radiation and Inorganic Analytical Services, 9 Ewing Street, Trenton, NJ 08625.
11. Natural uranium and thorium-230 are approved as gross alpha calibration standards for gross alpha with co-precipitation and evaporation methods; americium-241 is approved with co-precipitation methods.
12. If uranium (U) is determined by mass, a 0.67 pCi/µg of uranium conversion factor must be used. This conservative factor is based on the 1:1 activity ratio of U-234 to U-238 that is characteristic of naturally occurring uranium.

Table VI-2: Sample Handling, Preservation, and Instrumentation

Parameter	Preservative[1]	Container[2]	Maximum Holding Time[3]	Instrument-ation[4]
Gross Alpha	Conc. HCl or HNO_3 to pH <2[5]	P or G	6 mo	A, B, or G
Gross beta	Conc. HCl or HNO_3 to pH <2[5]	P or G	6 mo	A or G
Strontium-89	Conc. HCl or HNO_3 to pH <2[5]	P or G	6 mo	A or G
Strontium-90	Conc. HCl or HNO_3 to pH <2[5]	P or G	6 mo	A or G
Radium-226	Conc. HCl or[5] HNO_3 to pH <2	P or G	6 mo	A,B,D or G
Radium-228	Conc. HCl or HNO_3 to pH <2[5]	P or G	6 mo	A or G
Cesium-134	Conc. HCl to pH <2[5]	P or G	6 mo	A, C or G
Iodine-131	None	P or G	8 da	A, C or G
Tritium	None	G	6 mo	E
Uranium	Conc. HCl or HNO_3 to pH <2[5]	P or G	6 mo	F
Photon emitters	Conc. HCl or HNO_3 to pH <2[5]	P or G	6 mo	C

[1]It is recommended that the preservative be added to the sample at the time of collection unless suspended solids activity is to be measured. It is also recommended that samples be filtered, if suspended or settleable solids are present, prior to adding preservative, at the time of collection. However, if the sample has to be shipped to a laboratory or storage area, acidification of the sample (in its original container) may be delayed for a period not to exceed 5 days. A minimum of 16 hours must elapse between acidification and analysis.

[2]P = Plastic, hard or soft; G = Glass, hard or soft.

[3]Holding time is defined as the period from time of sampling to time of analysis. In all cases, samples should be analyzed as soon after collection as possible. If a composite sample is prepared, a holding time cannot exceed 12 months.

[4]A = Low background proportional system; B = Alpha and beta scintillation system; C = Gamma spectrometer [Ge(Hp) or Ge(Li)]; D = Scintillation cell system; E = Liquid scintillation system (section C.2.a); F = Fluorometer (section C.1.1); G = Low background alpha and beta counting system other than gas-flow proportional.

[5]If HCl is used to acidify samples which are to be analyzed for gross alpha or gross beta activities, the acid salts must be converted to nitrate salts before transfer of the samples to planchets.

Sample Forms for On-Site Evaluation of Laboratories Involved in Analysis of Public Water Supplies--Radiochemistry

Laboratory_____

Street_____

City_____State_____

Survey By_____

Affiliation_____

Date_____Telephone No._____

Laboratory_____Evaluator_____Date_
_____

Location_____
_____

PERSONNEL

Position/Title	Name	Academic Training	Present Specialty	Years Experience (chemistry)	Years Experience (radiochemistry)
Laboratory Director					
Quality Assurance Officer					
Section/Division chief/Director (if applicable)					
Supervisory Analyst					
Chemical Analyst(s)					
Chemical Technician(s)					
Computer Support Technician					
Electronics Support Technician					

Laboratory_____Evaluator_____Date_____

Location_____

LABORATORY FACILITIES

Item	Available		Comments
	Yes	No	
Laboratory			
Electrical outlets 120V ac. grounded			
Distilled or deionized water or ASTM type 1, 2, or 3			
Exhaust Hood			
Vacuum source			
Counting Room Separate from wet chemistry, sample and standards preparation area			
Regulated power supply			
Reagents			

Evaluator_____Date_____

Location_____

GENERAL LABORATORY EQUIPMENT AND INSTRUMENTS

Item	No.of Units	Manufacturer	Model	Satisfactory Yes	No
Analytical Balance 0.1 mg sensitivity stable base ASTM type 1 or 2 weights or better					
pH meter ±0.5 units readability ±0.1 units line or battery					
Conductivity meter Readable in ohms or mhos Range of 2 ohms or mhos Line or battery					
Drying oven gravity or convection controlled from room temp to 180°C or higher (±2°C)					
Infrared lamp may be substituted for drying oven					
Desiccator Glass or plastic					
Hot plate temperature control					
Refrigerator					
Magnetic Stirrer variable speed Teflon coated stir bar					
Balance, top loading					
Glassware					
Thermometers					
Muffle furnace to 450°C					
Centrifuge to 3000 rpm to hold 4 x 50 mL					

Laboratory_____Date_____

Location_____Evaluator_____

ALL INSTRUMENTATION

	Yes No	Comments
Are operating manuals readily available to the operator		
Are calibration protocols available to the operator		
Are calibrations kept in a permanent control chart		
Are permanent service maintenance records kept		

Laboratory_____Date_____

Location_____Evaluator_____

THIN WINDOW GAS-FLOW PROPORTIONAL COUNTER

Instrument number	Manufacturer	Model	Year	Sample Changing		
				Manual	Automatic	Capacity

Counting Gas	Window Density (g/cm^2)	Instrument Background			
		Alpha		Beta	
		Operating Voltage	cpm	Operating Voltage	cpm

Calibration Standard Type:	Calibration Frequency[1]				Service Maintenance Frequency[2]				Condition[3]		
Alpha	D	W	M	Other	Q	S	A	Other	G	R	N
Beta											
Supplier:											
Alpha											
Beta											

WINDOWLESS GAS-FLOW PROPORTIONAL COUNTER

Instrument number	Manufacturer	Model	Year	Sample Changing		
				Manual	Automatic	Capacity

Counting Gas	Window Density (g/cm^2)	Instrument Background			
		Alpha		Beta	
		Operating Voltage	cpm	Operating Voltage	cpm

Calibration Standard Type:Alpha	Calibration Frequency[1]				Service Maintenance Frequency[2]				Condition[3]		
Beta	D	W	M	Other	Q	S	A	Other	G	R	N
Supplier:											
Alpha											
Beta											

1. **D**aily, **W**eekly, **M**onthly.
2. **Q**uarterly, **S**emiannually, **A**nnually.
3. **G**ood, operating but needs **R**epair, **N**ot operating

Laboratory_____Date_____

Location_____Evaluator_____

LIQUID SCINTILLATION COUNTER

Instrument number	Manufacturer	Model	Year	Sample Changing		
				Manual	Auto	Capacity

Calibration Standard Type:	Calibration Frequency[1]				Service Maintenance Frequency[2]				Condition[3]		
	D	W	M	Other	Q	S	A	Other	G	R	N
Supplier:											

ALPHA SCINTILLATION COUNTER

Instrument number	Manufacturer	Model	Year	Sample Changing		
				Manual	Auto	Capacity

Calibration Standard Type:	Calibration Frequency[1]				Service Maintenance Frequency[2]				Condition[3]		
	D	W	M	Other	Q	S	A	Other	G	R	N
Supplier:											

RADON-GAS COUNTING SYSTEM

System number	Gas counting cells/system	Manufacturer of gas counting cell	Counting Instrument Make	Model	Year

	Calibration Frequency[1]				Service Maintenance Frequency[2]				Condition[3]		
	D	W	M	Other	Q	S	A	Other	G	R	N

1. **D**aily, **W**eekly, **M**onthly.
2. **Q**uarterly, **S**emiannually, **A**nnually.
3. **G**ood, operating but needs **R**epair, **N**ot operating

Laboratory_____Date_____

Location_____Evaluator_____

GAMMA SPECTROMETER SYSTEM

Detector System	System Number Type	Make	Model	Year	Size							
	Analyzer System Make	Model	Year	Channels								
Calibration Standard Type												
Supplier	Calibration Frequency D	W	M	Other	Service Maintenance Frequency Q	S	A	Other	Condition G	R	N	

OTHER APPROVED DETECTOR

Detector System	System Number Type	Make	Model	Year	Size							
	Analyzer System Make	Model	Year	Channels								
Calibration Standard Type												
Supplier	Calibration Frequency D	W	M	Other	Service Maintenance Frequency Q	S	A	Other	Condition G	R	N	

1. **D**aily, **W**eekly, **M**onthly.
2. **Q**uarterly, **S**emiannually, **A**nnually.
3. **G**ood, operating but needs **R**epair, **N**ot operating

Laboratory_____Date_____

Location_____Evaluator_____

SAMPLE HANDLING AND PRESERVATION

Parameter	Container Used	Preservative Used	Comments	Satisfactory Yes	Satisfactory No
Gross Alpha Activity					
Gross Beta Activity					
Strontium-89					
Strontium-90					
Radium-226					
Radium-228					
Cesium-134					
Iodine-131		NONE			
Tritium		NONE			
Uranium					
Photon Emitters					
a.					
b.					
c.					
d.					
e.					

Laboratory_____Date_____

Location_____Evaluator_____

METHODOLOGY

Parameter	**Sample Load/Mo**	**Method[1] Used - Cite Edition, Year, and Page**						**Satisfactory**	
		EPA	**SM1**	**ASTM**	**USGS**	**DOE**	**Other**	Yes	**No**
Gross Alpha Activity									
Gross Beta Activity									
Strontium-89									
Strontium-90									
Radium-226									
Radium-228									
Cesium-134									
Iodine-131									
Tritium									
Uranium									
Photon Emitters Identify:									
a.									
b.									
c.									
d.									
e.									

1 - Methods used must be referenced in the National Primary Drinking Water Regulations (40 CFR 141.25)

Laboratory_____Date_____

Location_____Evaluator_____

QUALITY CONTROL

Item	**Performance Evaluation Studies**	**A[1]**	**B[2]**	**Blind PE Studies**	**A[1]**	**B[2]**
Participation in performance evaluation and Blind PE studies Reporting Period: _____ to _____	Gross Alpha			Gross Alpha		
	Gross Beta			Gross Beta		
	Sr-89			Sr-89		
	Sr-90			Sr-90		
	Ra-226			Ra-226		
	Ra-228			Ra-228		
	Uranium			Uranium		
	Cs-134			Cs-134		
	Cs-137			Cs-137		
	Co-60			Co-60		
	Ba-133			Written QA Plan implemented and available for review		
	Zn-65					
	Tritium					
	I-131					
	Frequency	Yes	No	Comments	Satisfactory Yes	No
Duplicate analyses						
Spikes						
Failed PE studies						
Control charts						
Calibration and Maintenance records						

1 - Scheduled frequency of participation by the laboratory, times per year.
2 - Number of acceptable performance results in the past year, where an acceptable result is a normalized deviation from the known value of ≤ 3.0 sigma.

Laboratory_____Date_____

Location_____Evaluator_____

DATA REPORTING

Item	**Comments: systems used, frequency, etc.**
Records kept for 10 years Actual laboratory reports	
Tabular Summary	
Information included Date	
Place of sampling	
Time of sampling	
Sampler	
Date of sample receipt	
Date of analysis	
Type of analysis	
Laboratory & person responsible	
Other reported data	
Other reported data	
Method(s) used	
Results	

Appendix A
Chain-of-Custody Evaluations

A. Introduction

Written procedures for sample handling should be available and followed whenever samples are collected, transferred, stored, analyzed or destroyed. For the purposes of litigation, it is necessary to have an accurate written record to trace the possession and handling of samples from collection through reporting. The procedures defined here represent a means to satisfy this requirement.

A sample is in someone's "custody" if:

1. It is in one's actual physical possession;

2. It is in one's view, after being in one's physical possession;

3. It is one's physical possession and then locked up so that no one can tamper with it;

4. It is kept in a secured area, restricted to authorized personnel only.

B. Sample Collection, Handling and Identification

1. It is important that a minimum number of persons be involved in sample collection and handling. Guidelines established in standard manuals for sample collection preservation and handling should be used (e.g., EPA NPDES Compliance Sampling Inspection Manual, MCD 51, *Standard Methods for Examination of Water and Wastewater*). Field records should be completed at the time the sample is collected and should be signed or initialed, including the date and time, by the sample collector(s). Field records should contain the following information:

    a. Unique sample or log number;

    b. Date and time;

    c. Source of sample (including name, location and sample type);

    d. Preservative used;

    e. Analyses required;

    f. Name of collector(s);

    g. Pertinent field data (pH, DO, Cl residual, etc.);

    h. Serial number on seals and transportation cases;

    i. Comments.

2. Each sample is identified by affixing a pressure sensitive gummed label or standardized tag on the container(s). This label should contain the sample number, source of sample, preservative used, and the collector(s') initials. The analysis required should be identified. Where a label is not available, the sample information should be written on the sample container with an indelible marking pen. An example of a sample identification tag is illustrated in Figure A-1.

3. The closed sample container should then be placed in a transportation case along with the chain-of-custody record form, pertinent field records, and analysis request form. The transportation case should then be sealed and labeled. All records should be filled out legibly in waterproof pen. The use of locked or sealed chests will eliminate the need for close control of individual sample containers. However, there will undoubtedly be occasions when the use of a chest will be inconvenient. On these occasions, the sampler should place a seal around the cap of the individual sample container which would indicate tampering if removed.

C. Transfer of Custody and Shipment

1. When transferring the possession of the samples, the transferee must sign and record the date and time on the chain-of-custody record. Custody transfers, if made to a sample custodian in the field, should account for each individual sample, although samples may be transferred as a group. Every person who takes custody must fill in the appropriate section of the chain-of-custody record.

2. The field custodian (or field sampler if a custodian has not been assigned) is responsible for properly packaging and dispatching samples to the appropriate laboratory for analysis. This responsibility includes filling out, dating, and signing the appropriate portion of the chain-of-custody record. A recommended chain-of-custody format is illustrated in Figure A-2.

3. All packages sent to the laboratory should be accompanied by the chain-of-custody record and other pertinent forms. A copy of these forms should be retained by the field custodian (either carbon or photocopy).

4. Mailed packages can be registered with return receipt requested. If packages are sent by common carrier, receipts should be retained as part of the permanent chain-of-custody documentation.

5. Samples to be transported must be packed to prevent breakage. If samples are shipped by mail or by other common carrier, the shipper must comply with any applicable Department of Transportation regulations. (Most water samples are exempt unless quantities of preservatives used are greater than certain levels.) The package must be sealed or locked to prevent tampering. Any evidence of tampering should be readily detected if adequate sealing devices are used.

6. If the field sampler delivers samples to the laboratory, custody may be relinquished to laboratory personnel. If appropriate personnel are not present to receive the samples, they should be locked in a designated area of the laboratory to prevent tampering. The person delivering the samples should make a log entry stating where and how the samples were delivered and secured. Laboratory personnel may then receive custody by noting in a logbook, the absence of evidence of tampering, unlocking the secured area, and signing the custody sheet.

D. Laboratory Sample Control Procedures

Sample control procedures are necessary in the laboratory from the time of sample receipt to the time the sample is discarded. The following procedures are recommended for the laboratory:

1. A specific person must be designated as custodian and an alternate designated to act as custodian in the custodian's absence. All incoming samples must be received by the custodian, who must indicate receipt by signing the accompanying custody/control forms and who must retain the signed forms as permanent records.

2. The custodian must maintain a permanent logbook to record, for each sample, the person delivering the sample, the person receiving the sample, date and time received, source of sample, date the sample was taken, sample identification log number, how transmitted to the laboratory, and condition received (sealed, unsealed, broken container, or other pertinent remarks). This log should also show the movement of each sample within the laboratory; i.e., who removed the sample from the custody area, when it was removed, when it was

returned, and when it was destroyed. A standardized format should be established for logbook entries.

3. A clean, dry, isolated room, building, and/or refrigerated space that can be securely locked from the outside must be designated as a "custody room."

4. The custodian must ensure that heat-sensitive samples, light-sensitive samples, radioactive samples, or other sample materials having unusual physical characteristics, or requiring special handling, are properly stored and maintained prior to analysis.

5. Distribution of samples to the analyst performing the analysis must be made by the custodian.

6. The laboratory area must be maintained as a secured area, restricted to authorized personnel only.

7. Laboratory personnel are responsible for the care and custody of the sample once it is received by them and must be prepared to testify that the sample was in their possession and view or secured in the laboratory at all times from the moment it was received from the custodian until the time that the analyses are completed.

8. Once the sample analyses are completed, the unused portion of the sample, together with all identifying labels, must be returned to the custodian. The returned tagged sample must be retained in the custody room until permission to destroy the sample is received by the custodian.

9. Samples will be destroyed only upon the order of the responsible laboratory official when it is certain that the information is no longer required or the samples have deteriorated. (For example, standard procedures should include discarding samples after the maximum holding time has elapsed.) The same procedure is true for sample tags. The logbook should show when each sample was discarded or if any sample tag was destroyed.

10. Procedures should be established for internal audits of sample control information. Records should be examined to determine traceability, completeness, and accuracy.

Figure A-1 Sample Identification Tag Examples

U.S. EPA REGION

GENERAL CHEMISTRY

Official Sample No.

SOURCE

Date and Time

Sampler's Signature *Office*

Other Parameters:

PH	Acid
Cond	Alk
TS	SO_4
DS	Cl
SS	F
BOD_2	Cr. + 6
Turb	BOD_5
Color	

U.S. EPA REGION

MICROBIOLOGY

Official Sample No.

SOURCE

Date and Time

Sampler's Signature *Office*

Tot. Colif.

Fecal Colif.

Fecal Strep.

Salmonella

U.S. EPA REGION

PESTICIDES, ORGANICS

Official Sample No.

SOURCE

Date and Time

Sampler's Signature *Office*

Pesticides

PCB's:

Organics:

EPA

Station No.	Date	Time	Sequence No.
Station Location			_____ Grab _____ Comp.

_____ BOD
_____ Solids
_____ COD
_____ Nutrients
_____ Metals
_____ Oil and Grease
_____ D.O.
_____ Bact.
_____ Other

Remarks/Preservative:

Samplers:

○ⓒ®ᵛᵀᶜᴿ⅝ “¥½ —℗⅓ⓒ–¥¹⅞¥—ᵛᵀᴸᶠᴺᴸ¹⅜■ □⅝⅛¹ᶜᴿ⅜

–ᵛᵀᶜᴿ•⅝■				–⅓№ᴴᵀ‰ᵒ⅝ᶜᴿᴸᶠ¾ Signature					
Station Number	Station Location	Date	Time	Sample Type			Seq. No.	No. Of Containers	Analysis Required
				Water		Air			
				Comp	Grab				

Relinquished by: Signature	**Received by:** Signature	**Date/Time**
Relinquished by: Signature	**Received by:** Signature	**Date/Time**
Relinquished by: Signature	**Received by:** Signature	**Date/Time**
Relinquished by: Signature	**Received by Mobile Laboratory for Field analysis:** Signature	Date/Time

Dispatched by:	Date/Time	**Received for Laboratory by:** Signature	**Date/Time**
Method of Shipment:			

Distribution: Orig. --Accompany Shipment, 1 Copy--Survey Coordinator Field Files

Appendix B
Recommended Protocol for Regions Conducting On-Site Laboratory Evaluations

Before conducting the on-site evaluation, the Region should:

- Plan all the required activities to be completed during the assessment.

- Hold a pre-evaluation conference with appropriate laboratory and field activity representatives to establish a schedule that would have a minimum impact on the laboratory activities.

- Request and review appropriate records.

- Request that a variety of tests be scheduled during the on-site evaluation.

- Arrange for the laboratory staff to be available during the on-site visit.

During the on-site visit, the team shall:

- Conduct an opening conference or entrance interview.

- Evaluate the procedures and equipment used for those specific analyses for which the laboratory has requested certification, using the criteria in this manual.

- Review the records and written standard operating procedures for compliance with the required sampling frequency, sample collection, sample holding times, and if appropriate, resample notification.

- Perform a data audit on at least one sample and one PE sample for at least one method but preferably for each method the laboratory performs.

- Insure that the laboratory has a QA plan in effect by:

    - Determining if the laboratory has written procedures (QA plan or equivalent) for conducting its quality assurance program.

    - Examining the quality assurance data to determine if the quality assurance program is being implemented.

- Complete the on-site checklists and other evaluation forms during the visit (see Chapters IV, V, and VI).

- Conduct a closing conference or exit interview in which the auditors review the results of the evaluation with the director of the laboratory, the director of State water supply activities, and appropriate staff members. The review should:

    - Discuss any deviations in the observed procedures and records.

    - Recommend changes in equipment and supply needs, staffing requirements, and facility improvements, if necessary.

    - Discuss possible assistance the Region can provide the laboratory.

    - Discuss a time frame for corrective actions and response.

Evaluation Report for Principal State Laboratories and Laboratories in Non-Primacy States

After an on-site inspection, the evaluation team should prepare a narrative report and action memorandum. This report should contain all information pertinent to the evaluation and also recommend the certification status for all analyses evaluated. The report should then be forwarded for evaluation to the Certification Program Manager for review. After reviewing and, if necessary, revising the report, it should be forwarded to the Certification Authority for signature.

The Certification Authority should decide the certification status of the laboratory within time constraints on page III-7 and notify the State. The State should be sent the complete report. If the report indicates that the laboratory should not be certified for an analysis, the Certification Authority should give the specific reasons.

The narrative report should be attached to each copy of the completed evaluation form. It should include the general headings and information listed below.

Title Page
The title page should contain the following:

Title: Report of an on-site evaluation of the
(name of laboratory)
At: (city, state, and zip code)
On: (date)
By: (name, title, organization, and
address of the certification team)

Certification Status

List either "Certified", "Provisionally Certified", "Administratively/Interim Certified", or "Not Certified" for each contaminant evaluated or if applicable (for VOCs, for instance) for each class of compounds evaluated.

List of Deviations
List each deviation by item number used on the evaluation checklists. Describe the exact deviation and recommended changes.

Remarks
Recommend improvements which, while not affecting certification status, would improve laboratory operation. Other remarks might include reasons for failing the on-site evaluation, special recognition for outstanding performance, and description of unusual tests.

List of Personnel
List name and title of personnel along with the individual tests that each normally performs. Also, identify the critical laboratory personnel.

Signature
Team members should sign the report.

Distribution
Copies of this report should be distributed to the State requesting the evaluation. For local laboratories in non-primacy States, reports should be distributed to appropriate Regional personnel.

Annually, each Region should submit to OGWDW a listing of laboratories in the Region having U.S. EPA certification. The listing should include the names and location of each laboratory, and its certification status for all regulated contaminants. In addition, Regions should notify OGWDW of all changes in status soon after they occur so that OGWDW can maintain an updated list of certification status.

Appendix C
Definitions and Abbreviations

ASTM: American Society of Testing and Materials

AWWA: American Water Works Association

NERL-Ci: U.S. EPA National Exposure Research Laboratory in Cincinnati, Ohio (ORD).

NERL-LV: U.S. EPA National Exposure Research Laboratory in Las Vegas, Nevada (ORD).

NPDWR: National Primary Drinking Water Regulations.

OGWDW: U.S. EPA Office of Ground Water and Drinking Water.

ORD: U.S. EPA Office of Research and Development.

SDWA: The Safe Drinking Water Act as amended (42 U.S.C. 300f et seq.).

Accuracy: A measure of the closeness of an individual measurement or the average of a number of measurements to the true value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations. Refer to Standard Methods, Data Quality Section for a more detailed explanation.

Administrator: The administrator of the United States EPA or her/his authorized representative. See 40 CFR 142.2.

Agency: The U.S. EPA. See 40 CFR 142.2.

Auditor - A person who evaluates laboratories to determine if they meet the criteria to be certified. This person should be an experienced professional, who has effective communication skills, experience in quality assurance, the analytical techniques being evaluated, and familiarity with the drinking water regulations and this manual.

Bachelor Degree or Equivalent: A college degree with an equivalent 30 semester hours in a specific discipline. Equivalent is at least four years of experience in a specific scientific discipline.

Bias: The systematic or persistent distortion of a measurement process which causes errors in one direction.

Certification Authority: (CA) The person or designee who has the authority to certify laboratories conducting drinking water analyses and to certify the officials of the State responsible for the State's certification program in accordance with Section 1412 of the Safe Drinking Water Act. This authority is delegated to the Regional Administrator but may be redelegated.

Certification Program Manager: (CPM) The person responsible for managing the certification program which includes tracking the certification status of the State laboratories, ensuring that the regional and State certification officers are qualified and reviewing the certification evaluation reports.

Certification Officer: (CO) A State or Federal laboratory auditor who has passed the NERL certification officers training course (limited at this time to chemistry and microbiology). This person provides information to the CA or CPM for the purpose of making decisions on the certification status of a laboratory.

CFR: Code of Federal Regulations - A compilation of regulations is revised each time a regulation is promulgated. It is published every year in July.

Confirmation: Verification of the presence of a component through the use of an analytical technique based on a different scientific principle from the original method (e.g., second column, alternate wavelength or detector, etc.)

Data Audit: A qualitative and quantitative evaluation of the documentation and procedures associated with measurements to verify that the resulting data are acceptable.

Data Quality Objectives: qualitative and quantitative specifications used to design a study that will limit uncertainty to an acceptable level.

Data Reduction: The process of transforming the number of data items by arithmetic or statistical calculations, standard curves, concentration factors, etc. and collation into a more useful form. Data reduction is irreversible and generally results in the loss of detail.

Detection: Any concentration of an analyte which equals or exceeds the laboratory's detection limit. For VOCs, detection limit is defined as 0.0005 mg/L.

Drinking Water Laboratory: A laboratory that analyses samples as part of compliance monitoring for a public water supply.

Federal Indian Land: Areas which for regulatory purposes are treated as independent States. On these lands, the Indian tribe has a Federally recognized governing body carrying out government duties and powers.

Holding time: The allowed time from when a sample was taken (or extracted) until it must be analyzed.

IDC: Initial Demonstration of Capability - before analyzing compliance samples an analytical team must demonstrate acceptable precision, accuracy, sensitivity, and specificity for the method to be used.

LRB - Laboratory Reagent Blank: (Method blank) An aliquot of reagent water or other blank matrix that is treated exactly as a sample to determine if method analytes or other interferences are present.

LFB - Laboratory Fortified Blank: (Spike) An aliquot of reagent water or other blank matrix to which known quantities of the method analytes are added in the laboratory. The LFB is analyzed exactly like a sample to determine whether the method is in control.

MCL: Maximum contaminant level means the maximum permissible level of a contaminant in water which is delivered to any user of a public water system. See 40 CFR Part 141.2.

MCLG: Maximum contaminant level goal means the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. Maximum contaminant level goals are nonenforceable health goals. See 40 CFR 141.2.

Method Detection Limit: (MDL) is defined as the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero. The MDL is determined from analysis of a sample in a given matrix containing this analyte. See 40 CFR 136 App. B.

Monitoring Trigger: The concentration of a regulated contaminant which triggers additional monitoring

NELAC: National Environmental Laboratory Accreditation Conference - a voluntary organization of State, Federal and other groups to establish mutually acceptable standards for accrediting environmental laboratories.

Performance Evaluation Samples (PEs): (Proficiency test sample) A sample provided to a laboratory for the purpose of demonstrating that the laboratory can successfully analyze the sample within specified acceptance limits specified in the regulations. The qualitative and/or quantitative composition of the reference material is unknown to the laboratory at the time of the analysis. See 40 CFR Part 141.2.

Precision: The measure of mutual agreement among individual measurements.

Primacy: Primary responsibility for administration and enforcement of primary drinking water regulations and related requirements applicable to public water systems within a State

Principal State Laboratory System: All facilities, whether part of the State laboratory or contracted to the State, producing data for the State and certified by the EPA, fulfilling the requirements for Primacy as listed in the 40 CFR 142.10(b)(4).

Public Water System: A system for the provision to the public of piped water for human consumption, if such system has at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year. See 40 CFR Part 141.2.

Quality Assurance: An integrated system of management activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

Quality Control: The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of the users; operational techniques and activities that are used to fulfill requirements for quality.

QA Plan: A comprehensive plan detailing the aspects of quality assurance needed to adequately fulfill the data needs of a program. This document is required before the laboratory is certified.

Regulatory Level: A concentration of a contaminant which is cited in the Federal Regulations (e.g., MCL, detect, etc.)

Shall: Denotes a mandatory requirement.

Should: Denotes a guideline or recommendation.

Standard Operating Procedure: A written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is officially approved as the method for performing certain routine or repetitive tasks.

Third Party Auditor: Person or persons, not affiliated with a Region or State, who is designated by the Region or State to audit a laboratory. This person must pass the certification training course prior to auditing any laboratory unless he or she is a part of an audit team which includes a Regional/State certification officer. The third party auditor must also meet the educational/experience requirements specified in this manual. The certification decision remains with the Region.

Third Party Expert: Any person not designated as a certification officer or auditor, who is requested by the Region to assist in the audit of a laboratory because of his or her expertise in a particular area (e.g., asbestos). This person is not required to take the certification officers' course if he or she is part of an audit team which includes a certification officer.

"Unregulated" Contaminants: Contaminants for which monitoring is required but which have no MCL.

Appendix D

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 16,1997

MEMORANDUM

SUBJECT: The Use of "Third-Parties" in the Drinking Water Laboratory Certification Program

FROM: Cynthia Dougherty, Director
Office of Ground Water and Drinking Water

TO: Water Supply Representatives, Regions I-X
Certification Authorities, Regions I-X
Quality Assurance Officers, Regions I-X
Regional Laboratories, Regions I-X

Purpose
This memorandum updates and clarifies the guidance memorandum from Michael Cook dated December 5, 1989 on "Third-Party Certification for Laboratories in Primacy States."

Action
Under 40 CFR 142.10(b) (3), if a State does not perform all analytical measurements in its own laboratory, it must establish and maintain a program for the certification of laboratories as a condition for receiving and maintaining authority to administer the Safe Drinking Water Act in lieu of EPA (primacy). This memorandum notifies States with primacy that they may contract with other organizations (third parties) to assist the State in fulfilling this requirement. The authority for making certification decisions however, must remain with the State.

Discussion
Several States have asked USEPA its position on the use of third-parties, i.e., private sector organizations which assist the States with their certification program. OGWDW realizes that dwindling State resources may necessitate assistance from third-parties in the State certification programs. Consistent with the regulatory requirement at 40 CFR 142.10(b), providing for the "establishment and maintenance of a State program for the certification of laboratories," the State must retain ultimate authority to decide whether individual laboratories will be certified: this decision

may not be abdicated to the third party.

This Office will not pass judgment on any specific third-party program. It is the responsibility of each primacy State to assess the qualifications of the third-party. In assessing whether to choose a particular third-party, the State should consider, as a minimum, the following items which are described in the *Manual for the Certification of Laboratories Analyzing Drinking Water*:

- **Ability to provide technical assistance and training**
- **Availability of records for review by the State**
- **Quality assurance program**
- **Freedom from conflicts of interest**
- **EPA policy, which provides that the auditor should pass an appropriate course on how to audit in the discipline for which he or she will be auditing.**
- **Experience of the auditor.**

  The auditor should be an experienced professional with at least a bachelor's degree or equivalent education/experience in the discipline for which he or she audits.

  The auditor should have recent laboratory experience

Any State certification program using third party assistance should meet the requirements in the *Manual for the Certification of Laboratories Analyzing Drinking Water* just as it would if it were using State employees to perform these functions. The Regions should assist the State and third-party agent to assure that the certification program meets EPA guidelines.

Regions and States should be sensitive to potential conflict-of-interest problems between a third-parties and evaluated laboratories. For instance, inspectors employed by firms that provide analytical services in the drinking water area should not be put in the position of passing judgement on their competitors.

Further Information
If you have questions or need additional information or assistance, please contact the OGWDW Technical Support Center at 513-569-7904.

Appendix E
Required Analytical Capability for Principal State Laboratory Systems

INORGANICS
(40 CFR 141.23)
Asbestos
Cyanide
Fluoride
Nitrate
Nitrite
Antimony
Arsenic
Barium
Beryllium
Cadmium
Chromium
Mercury
Selenium
Thallium
(40 CFR 141.89)
Copper
Lead
Conductivity
Calcium
Alkalinity
Orthophosphate
Silica

VOLATILE ORGANICS
(40 CFR 141.24)
THMs
Benzene
Carbon tetrachloride
Chlorobenzene
o-Dichlorobenzene
p-Dichlorobenzene
1,2-Dichloroethane
1,1-Dichloroethylene
cis-1,2-Dichloroethylene
trans-1,2-Dichloroethylene
Dichloromethane
1,2-Dichloropropane
Ethylbenzene
Styrene
Tetrachloroethene
Toluene
1,2,4-Trichlorobenzene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichloroethene
Vinyl chloride
Xylenes

MICROORGANISMS
(40 CFR 141.21)
Total coliforms
Escherichia coli or fecal coliforms
Heterotrophic bacteria

SOCs
(40 CFR 141.24)
Alachlor
Atrazine
Benzo(a)pyrene
Carbofuran
Chlordane
2,4-D
Di(2-ethylhexyl)adipate
Di(2-ethylhexyl)phthalate
Dibromochloropropane
Dalapon
Dinoseb
Dioxin (2,3,7,8-TCDD)
Diquat
Endothall
Endrin
Ethylenedibromide
Glyphosate
Heptachlor
Heptachlor epoxide
Hexachlorobenzene
Hexachlorocyclopentadiene
Lindane
Methoxychlor
Oxamyl
PCBs (as decachlorobiphenyl)
Pentachlorophenol
Picloram
Simazine
Toxaphene
2,4,5-TP

RADIONUCLIDES
(40 CFR 141.25)
Gross Alpha
  Uranium
Gross Beta
  Cesium-134
  Strontium-89
  Iodine-131
  Strontium-90
  Tritium
  Other beta/photon emitters
Radium-226/228

Appendix F
Unregulated, Proposed and Secondary Contaminants

UNREGULATED VOCs
(40 CFR 141.40)
Bromobenzene
Bromodichloromethane
Bromoform
Bromomethane
Chlorodibromomethane
Chloroethane
Chloroform
Chloromethane
o-Chlorotoluene
p-Chlorotoluene
1,1-Dichloroethane
1,3-Dichloropropane
2,2-Dichloropropane
1,1-Dichloropropene
1,3-Dichloropropene(c/t)
m-Dichlorobenzene
Dibromomethane
1,1,1,2-Tetrachloroethane
1,1,2,2-Tetrachloroethane
1,2,3-Trichloropropane

UNREGULATED IOCs
(40 CFR 141.40)
Corrosivity
Sodium
Sulfate

PHASE 6A
(Proposed 7/29/94)
Free & Total Chlorine
Combined Chlorine
Chlorine Dioxide
Trihalomethanes
Haloacetic Acids
Bromate
Chlorite
Total Organic Carbon
Alkalinity
Bromide

UNREGULATED SOCs
(40 CFR 141.40)
Aldicarb
Aldicarb Sulfoxide
Aldicarb Sulfone
Aldrin
Butachlor
Carbaryl
Dicamba
Dieldrin
3-Hydroxycarbofuran
Methomyl
Metolachlor
Metribuzin
Propachlor

RADIONUCLIDES
(Proposed 7/18/91)
(40 CFR 141.25)
Radon
Uranium
(40 CFR 141.44)
Lead-210

SECONDARY CONTAMINANTS
Aluminum
Chloride
Color
Copper
Fluoride
Foaming Agents
Iron
Manganese
Odor
pH
Silver
Sulfate
Total Dissolved Solids (TDS)
Zinc

Contaminants to be Monitored at the Discretion of the State

1,2,4-Trimethylbenzene
1,2,3-Trichlorobenzene
n-Propylbenzene
n-Butylbenzene
Naphthalene
Hexachlorobutadiene
1,3,5-Trimethylbenzene
p-Isopropyltoluene
Isopropylbenzene
tert-Butylbenzene
sec-Butylbenzene
Fluorotrichloromethane
Dichlorodifluoromethane
Bromochloromethane

Appendix G

Analytical Methods for Microbiology

1. Total Coliform Rule (40 CFR 141.21(f))

(f) *Analytical methodology*. (1) The standard sample volume required for total coliform analysis, regardless of analytical method used, is 100 mL.

(2) Public water systems need only determine the presence or absence of total coliforms; a determination of total coliform density is not required.

(3) Public water systems must conduct total coliform analyses in accordance with one of the analytical methods in the following table. These methods are contained in the 18th edition of *Standard Methods for the Examination of Water and Wastewater*, 1992, American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005. A description of the Colisure Test may be obtained from the Millipore Corporation, Technical Services Department, 80 Ashby Road, Bedford, MA 01730. The toll-free phone number is (800) 645-5476.

Organism	Methodology	Citation
Total Coliforms[1]	Total Coliform Fermentation Technique [2,3,4]	9221A,B
	Total Coliform Membrane Filter Technique	9222A,B,C
	Presence-Absence (P-A) Coliform Test[4,5]	9221D
	ONPG-MUG Test[6]	9223
	Colisure Test[7]	

[1] The time from sample collection to initiation of analysis may not exceed 30 hours. Systems are encouraged but not required to hold samples below 10°C during transit.

[2] Lactose broth, as commercially available, may be used in lieu of lauryl tryptose broth, if the system conducts at least 25 parallel tests between this medium and lauryl tryptose broth using the water normally tested, and this comparison demonstrates that the false-positive rate and false-negative rate for total coliforms, using lactose broth, is less than 10 percent.

[3] If inverted tubes are used to detect gas production, the media should cover these tubes at least one-half to two-thirds after the sample is added.

[4] No requirement exists to run the completed phase on 10 percent of all total coliform-positive confirmed tubes.

[5] Six-times formulation strength may be used if the medium is filter-sterilized rather than autoclaved.

[6] The ONPG-MUG Test is also known as the Autoanalysis Colilert System.

[7] The Colisure Test must be incubated for 28 hours before examining the results. If an examination of the results at 28 hours is not convenient, then results may be examined at any time between 28 hours and 48 hours.

(4) [Reserved]

(5) Public water systems must conduct fecal coliform analysis in accordance with the following procedure. When the MTF Technique or Presence-Absence (PA) Coliform Test is used to test for total coliforms, shake the lactose-positive presumptive tube or P-A [bottle] vigorously and transfer the growth with a sterile 3-mm loop or sterile applicator stick into brilliant green lactose bile broth and EC medium to determine the presence of total and fecal coliforms,

respectively. For EPA-approved analytical methods which use a membrane filter, transfer the total coliform-positive culture by one of the following methods: remove the membrane containing the total coliform colonies from the substrate with a sterile forceps and carefully curl and insert the membrane into a tube of EC medium (the laboratory may first remove a small portion of selected colonies for verification), swab the entire membrane filter surface with a sterile cotton swab and transfer the inoculum to EC medium (do not leave the cotton swab in the EC medium), or inoculate individual total coliform-positive colonies into EC Medium. Gently shake the inoculated tubes of EC medium to insure adequate mixing and incubate in a waterbath at 44.5 ±0.2 °C for 24 ±2 hours. Gas production of any amount in the inner fermentation tube of the EC medium indicates a positive fecal coliform test. The preparation of EC medium is described in the 18th edition of *Standard Methods for the Examination of Water and Wastewater*, 1992, Method 9221E-p. 9-52, paragraph 1a. Public water systems need only determine the presence or absence of fecal coliforms; a determination of fecal coliform density is not required.

(6) Public water systems must conduct analysis of Escherichia coli in accordance with one of the following analytical methods:

(i) EC medium supplemented with 50 µg/mL of 4-methylumbelliferyl-beta-D-glucuronide (MUG) (final concentration). EC medium is described in the 18th edition of *Standard Methods for the Examination of Water and Wastewater*, 1992, Method 9221E-p. 9-52, paragraph 1a. MUG may be added to EC medium before autoclaving. EC medium supplemented with 50 µg/mL of MUG is commercially available. At least 10 mL of EC medium supplemented with MUG must be used. The inner inverted fermentation tube may be omitted. The procedure for transferring a total coliform-positive culture to EC medium supplemented with MUG shall be as specified in paragraph (f)(5) of this section for transferring a total coliform-positive culture to EC medium. Observe fluorescence with an ultraviolet light (366 nm) in the dark after incubating tubes at 44.5 ±0.2 °C for 24 ±2 hours; or

(ii) Nutrient agar supplemented with 100 µg/mL 4-methylumbelliferyl-beta-D-glucuronide (MUG) (final concentration). Nutrient Agar is described in the 18th edition of *Standard Methods for the Examination of Water and Wastewater*, 1992, p. 9-47 to 9-48. This test is used to determine if a total coliform-positive sample, as determined by the Membrane Filter Technique or any other method in which a membrane filter is used, contains E. coli. Transfer the membrane filter containing a total coliform colony(ies) to nutrient agar supplemented with 100 µg/mL (final concentration) of MUG. After incubating the agar plate at 35 °C for 4 hours, observe the colony(ies) under ultraviolet light (366 nm) in the dark for fluorescence. If fluorescence is visible, E. coli are present.

(iii) Minimal Medium ONPG-MUG (MMO-MUG) Test, as set forth in the article "National Field Evaluation of a Defined Substrate Method for the Simultaneous Detection of Total Coliforms and Escherichia coli from Drinking Water: Comparison with Presence-Absence Techniques" (Edberg et al.), Applied and Environmental Microbiology, Volume 55, pp. 1003-1008, April 1989. (Note: The Autoanalysis Colilert System is an MMO-MUG test). If the MMO-MUG test is total coliform-positive after a 24-hour incubation, test the medium for fluorescence with a 366-nm ultraviolet light (preferably with a 6-watt lamp) in the dark. If fluorescence is observed, the sample is E. coli-positive. If fluorescence is questionable (cannot be definitively read) after 24 hours incubation, incubate the culture for an additional four hours (but not to exceed 28 hours total), and again test the medium
for fluorescence. The MMO-MUG Test with hepes buffer in lieu of phosphate buffer is the only approved formulation for the detection of E. coli.

(iv) The Colisure Test. A description of the Colisure Test +may be obtained from the Millipore Corporation, Technical Services Department, 80 Ashby Road, Bedford, MA 01730.

(7) As an option to paragraph (f)(6)(iii) of this section, a system with a total coliform-positive, MUG-negative, MMO-MUG test may further analyze the culture for the presence of E. coli by transferring a 0.1 mL, 28-hour MMO-MUG culture to EC Medium + MUG with a pipet. The formulation and incubation conditions of EC Medium + MUG, and observation of the results are described in paragraph (f)(6)(i) of this section.

2. Surface Water Treatment Rule (40 CFR 141.74(a))

(a) *Analytical requirements.* Only the analytical method(s) specified in this paragraph, or otherwise approved by EPA, may be used to demonstrate compliance with the requirements of § 141.71, 141.72, and 141.73. Measurements for pH, temperature, turbidity, and residual disinfectant concentrations must be conducted by a party approved by the State. Measurements for total coliforms, fecal coliforms, and HPC must be conducted by a laboratory certified by the State or EPA to do such analysis. Until laboratory certification criteria are developed for the analysis of HPC and fecal coliforms, any laboratory certified for total coliform analysis by EPA is deemed certified for HPC and fecal coliform analysis. The following procedures will be performed in accordance with the publications listed in the following section. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the methods published in *Standard Methods for the Examination of Water and Wastewater* may be obtained from the American Public Health Association et al., 1015 Fifteenth Street, NW, Washington, D.C. 20005; copies of the Minimal Medium ONPG-MUG Method as set forth in the article "National Field Evaluation of a Defined Substrate Method for the Simultaneous Enumeration of Total Coliforms and Escherichia coli from Drinking Water: Comparison with the Standard Multiple Tube Fermentation Method" (Edberg et al.), Applied and Environmental Microbiology, Volume 54, pp. 1595-1601, June 1988 (as amended under Erratum, Applied and Environmental Microbiology, Volume 54, p. 3197, December 1988), may be obtained from the American Water Works Association Research Foundation, 6666 West Quincy Avenue, Denver, Colorado, 80235; and copies of the Indigo Method as set forth in the article "Determination of Ozone in Water by the Indigo Method" (Bader and Hoigne), may be obtained from Ozone Science & Engineering, Pergamon Press Ltd., Fairview Park, Elmsford, New York 10523. Copies may be inspected at the U.S. Environmental Protection Agency, Room EB15, 401 M Street, SW., Washington, D.C. 20460 or at the Office of the Federal Register, 1100 L Street, NW, Room 8401, Washington, D.C.

(1) Public water systems must conduct analysis of pH and temperature in accordance with one of the methods listed at §141.23(k)(1). Public water systems must conduct analysis of total coliforms, fecal coliforms, heterotrophic bacteria, and turbidity in accordance with one of the following analytical methods and by using analytical test procedures contained in Technical Notes on Drinking Water Methods, EPA-600/R-94-173, October 1994, which is available at NTIS PB95-104766.

Organism	Methodology	Citation[1]
Total Coliforms[2]	Total Coliform Fermentation Technique[3,4,5]	9221A,B,C
	Total Coliform Membrane Filter Technique	9222A,B,C
	ONPG-MUG Test[6]	9223
Fecal Coliforms[2]	Fecal Coliform Procedure[7]	9221E
	Fecal Coliform Membrane Filter Procedure	9221D
Heterotrophic bacteria[2]	Pour Plate Method	9215B
Turbidity	Nephelometric Method	2130B
	Nephelometric Method	180.1[8]
	Great Lakes Instruments	Method 2[9]

[1] Except where noted, all methods refer to the 18th edition of *Standard Methods for the Examination of Water and Wastewater*, 1992, American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005.

[2] The time from sample collection to initiation of analysis may not exceed 8 hours. Systems are encouraged but not required to hold samples below 10°C during transit.

[3] Lactose broth, as commercially available, may be used in lieu of lauryl tryptose broth, if the system conducts at least 25 parallel tests between this medium and lauryl tryptose broth using the water normally tested, and this comparison demonstrates that the false positive rate and false negative rate for total coliforms, using lactose broth, are less than 10 percent.

[4] Media should cover inverted tubes at least one-half to two-thirds after the sample is added.

[5] No requirement exists to run the completed phase on 10 percent of all total coliform-positive confirmed tubes.

[6] The ONPG-MUG Test is also known as the Autoanalysis Colilert System.

[7] A-1 Broth may be held up to three months in a tightly closed screwcap tube at 4°C.

[8] "Methods for the Determination of Inorganic Substances in Environmental Samples," EPA-600/R-93-100, August 1993. Available at NTIS, PB94-121811.

[9] GLI Method 2, "Turbidity," November 2, 1992, Great Lakes Instruments, Inc., 8855 North 55th Street, Milwaukee, Wisconsin 53223.

Appendix H

Record Audits for Drinking Water Laboratories

Introduction

This Appendix provides information on the records which drinking water laboratories should maintain. It is intended to assist the certification officer in conducting data audits for drinking water laboratories. Certification officers should use the criteria in this Appendix, as well as appropriate earlier chapters, for evaluating all laboratories. Evaluation of adequate record keeping/documentation can be facilitated by using the checklists (Chemistry, Microbiology, and Radiochemistry) at the end of this Appendix. Auditors are encouraged to develop their own more comprehensive checklists, using these as a starting point. The data audit information in the microbiology checklists (pp. H-21 to H-24) is also included in Chapter 5. The Chapter 5 checklist supersedes this checklist which is included here only for appendix completeness.

Implementing the recommended record keeping/documentation specified in this appendix will facilitate an "audit of data quality," the tracking of one or more data points from sample receipt by the laboratory (or from sample collection and preservation, if conducted by the laboratory), through preparation, analysis, interpretation, calculations, recording, and reporting of results. All necessary documentation in laboratory records for each step in the data generation process pertaining to any data point should be readily available for the auditor. By tracking this information, the auditor can better assess the quality of data routinely generated by the laboratory.

If any criterion in this Appendix differs from a criterion in a specific EPA-approved method, the method takes precedence, because its use is required by regulations.

Data Audits

The EPA Quality Assurance Glossary and Acronyms (February 1991) defines an audit of data quality as:

> "A quantitative and qualitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality."

The data audit is typically performed on-site and involves tracing the paper and electronic trail of an individual sample or samples from the time of sample collection to the preparation of the final report. Auditors should be competent scientists who are familiar with methodology, the particular data collection technology and QC procedures.

When a data audit is to be performed, the first step is to read the pertinent standard operating procedures (SOPs), and generate a checklist of items to be examined. Procedures should be verified for sample collection, receipt, storage, preparation, analysis, reporting, and all associated QC.

A checklist should be prepared prior to the on-site visit. When the on-site audit takes place, the sample or samples to be examined should be chosen at random. One of the samples audited should be the most recent PE sample. Sample log- in records, laboratory notebooks, extraction records, analysis records and any other documents necessary to confirm that procedures were followed as described, should be examined.

The audit report should cite deficiencies, if any, in the procedures and/or documentation and suggested corrective actions.

The data audit process involves reviewing all records that document the sampling, storage and data generation processes from beginning to end. Individual laboratories may use a variety of systems for recording, reporting, and storing such information -- including both manual and automated techniques. In addition, the specific information

recorded by laboratories may differ based on standard operating procedures and information storage and retrieval systems. The auditor should be able to reconstruct the final reported data for a field or performance evaluation sample. A comparison of raw PE data to raw data for standards should verify that the laboratory has analyzed the PE sample at the correct dilution.

Records to be Reviewed

This Appendix describes documentation needed to document the sampling, storage and data generation processes. These items constitute the minimum suite of records that should comprise a comprehensive laboratory record keeping system. Not all records apply to all types of drinking water analyses and the specific records needed at a laboratory will depend on the analyses the laboratory runs. Records of laboratory analyses will vary with the method and instrumentation used. For example, calibration records will be more detailed for instruments used in organic and inorganic chemical analyses than for microbiological analyses. Field sampling and data recording and reporting records apply to all analyses.

The laboratory should record all information on individual data sheets or in a log book using ink. Original entries should not be obliterated. Corrections should be made with a single line through the entry, initialed and dated. All records maintained electronically should be secured to prevent unauthorized changes. **If the laboratory changes to a new system, all records should either be transferred to the new system or saved in hard copy format.** All records should be archived in an organized manner that allows easy retrieval. The ease with which laboratory managers are able to retrieve data generation records may be the auditor's first indication of the completeness and effectiveness of the laboratory data generation and record keeping system. Record keeping systems should allow correlation between system and laboratory identification codes.

If a laboratory uses a subcontract laboratory for certain analyses, data provided by subcontract laboratories should be clearly identified as such and any needed documentation at the subcontract laboratory should be available to the auditor upon request.

Drinking water compliance data pertaining to chemical and radiological analyses must be stored and retained by the utility for a period of ten years as required by 40 CFR 141.33. Data pertaining to microbiological analyses must be retained for five years. Data for lead and copper (CFR 141.91) must be maintained for 12 years. It is recommended that the laboratory maintain the compliance sample and QC data for at least five years or until the next audit, whichever is longer. See Chapters IV, V, and VI, Section 8.2. Data should be stored in a manner that allows efficient and accurate retrieval. The auditor should review the data storage and retrieval system carefully to determine whether proper procedures are followed. If a laboratory is unable to locate data requested by the auditor or requires an inordinate period of time to retrieve requested data, the auditor should consider the data storage system deficient.

To assist auditors in conducting data and record keeping audits, a series of checklists has been developed and are included at the end of this Appendix. These checklists include specific items which should be checked during the data audit of an individual field or PE sample.

1.0 Field Sampling

1.1 *Sampling Records*

At the time of sample collection, field personnel should record the information listed in the Sample Checklist (page H-13, Field Sampling) on a sample tracking form or electronically for each sample.

A sample tracking record should be maintained for samples. This record should be made in indelible ink or electronic form and should identify the sample collector, the person or persons transporting the samples from the system to the laboratory, as well as the individual(s) who received the samples and the condition of the sample upon receipt. If a

commercial shipper was used, shipping records should be available.

Sample collection (and related data recording and record keeping) may not be within the scope of the laboratory's responsibilities. Some field records therefore may not be available to or maintained by the laboratory. Either the laboratory or the organization responsible for sample collection should keep records describing how the sample containers were prepared (i.e., cleaning methods, sterilization technique/date/time/batch number) and how preservatives were prepared and how the samples were collected. In all cases, the sample tracking record and shipping form (if available) should accompany samples to the laboratory, and this documentation, at a minimum, should be maintained by the laboratory. Documentation should be available to verify that SOPs were used for sample collection and that the sample collectors were properly trained.

1.2 *Field Analytical Records*

Field measurements made for parameters that are dynamic should be made immediately. If a laboratory conducts analyses in the field (i.e., temperature, free residual chlorine, and pH), field personnel should record the items listed in the Sample Checklist on page H-13, Field Measurements. Calibrations should be performed in the field over a range of concentrations that bracket the concentrations measured in the unknown samples. For chemical analyses, the lowest concentration used in a calibration should be at least as low as the pertinent regulatory level. Thermometers should be calibrated annually using a reference thermometer traceable to the National Institute of Standards and Technology. Residual free chlorine comparison devices such as color wheels and their application by field personnel should be checked semiannually. Procedures for field calibrations of instruments should be documented in standard operating procedures for field activities.

1.3 *Sample Inspection and Acceptance Policy*

When samples arrive at the laboratory, whether by mail or other carrier, the laboratory should check samples and sample records to verify that the required preservation steps and holding times have been adhered to. Laboratory personnel should check sample and shipping containers for integrity (e.g., leaks, cracks, broken seals) and for any obvious signs of improper collection (e.g., head space in VOC samples). The laboratory should verify that proper shipping procedures were followed (e.g., ice should still be present with samples collected for organic analyses). This information should be recorded. In larger laboratories, sample custodians should be designated to perform this function and automated laboratory sample tracking systems may be used to record sample receipt and destination. When a bar code is used, the laboratory should calibrate the bar code reader periodically and document the calibration.

The laboratory should add the bullet items in the Sample Checklist (page H-14, Sample Acceptance) to the sample tracking form for each sample at the time of receipt:

1.4 *Sample Storage*

The auditor should visit the sample receiving area of the laboratory and inspect the condition of samples to determine that container labels are properly completed and securely attached and that all necessary information is recorded by the laboratory. The auditor should also verify that samples requiring special handling (e.g., light sensitive, temperature sensitive, radioactive) are properly stored and that samples are analyzed within their holding times.

Before analysis, the analyst should check samples for the proper preservation technique, pH, chlorine residual, etc. Errors in sample preservation and/or handling are known to bias analytical results. Laboratories must reject compliance samples which do not comply with the method sampling and preservation requirements and request a replacement sample.

2.0 Laboratory Analysis

2.1 *Analytical Methods*

Each laboratory should list and have on hand, in its Quality Assurance Plan, the SOPs (which include the analytical method) for each drinking water analyte measured. This listing should include the name of the method and a complete reference or source (e.g., 18th Edition of ***Standard Methods for Examination of Water and Wastewater***, with method number). The auditor should verify that the methods listed are EPA-approved for drinking water (or otherwise acceptable to EPA), that a copy of the method is available to the analyst, and that the methods listed are the only ones actually being used for the analysis of the drinking water compliance samples.

Laboratories should have written SOPs for all analyses and laboratory procedures. The SOPs delineate the specific procedures used to carry out the methods and how, if at all, the SOP differs from the required method. The purpose of the SOPs is to specify analytical procedures in greater detail than appears in the published method in order to further ensure that analyses are conducted in a standard manner by all analysts in a laboratory. The auditor should verify that analysts are following the written SOPs and that the SOPs are consistent with EPA approved analytical methods for drinking water and any deviations are clearly identified. The SOPs should be available in the laboratory at the analyst's work station.

2.2 *Instrument Performance*

Instrument and equipment performance is a significant factor in laboratory data quality. Consequently, the laboratory should monitor and document instrument/equipment performance characteristics regularly, in accordance with method specifications and the recommendations of equipment manufacturers. For all instruments/equipment, the bullet items in the Checklist (page H-15, Instrument Performance) should be maintained (insofar as they apply to analyses conducted by the laboratory).

Performance records are important for all instruments and equipment used to perform drinking water analyses, including analytical balances, incubators, refrigerators, autoclaves, water baths, and block digestors. For such equipment, routine calibrations against standards traceable to the National Institute of Standards and Technology (NIST) should be performed.

ASTM type 1 or 2 weights or better should be available to make daily checks on balances. A record of these checks should be available for inspection. The specific checks and their frequency should be as prescribed in the laboratory's QA plan and the laboratory's operations manual, if appropriate. The ASTM weights should be recertified annually.

Wavelengths on spectrophotometers should be verified daily with color standards. A record of these checks should be available for inspection. The specific checks and their frequency should be as prescribed in the laboratory's SOPs.

Proper maintenance of all laboratory instruments/equipment is critical to achieving proper laboratory performance. Instrument manufacturers provide suggested maintenance schedules and laboratories should adhere to such schedules. Laboratories should also record maintenance and repair activities for all instruments, including both determinative instruments (e.g., specific ion detectors, spectrophotometers, etc.) and non-determinative equipment (e.g., incubators, ovens, balances, etc.). Maintenance logs should also list the maintenance schedule and the date and name of the individual(s) performing routine instrument maintenance.

2.3 *Initial Demonstration of Capability*

The initial demonstration of capability (IDC) ensures that the analyst and the method are capable of measuring the analytes of interest within the acceptance criteria necessary to comply with the regulations. The IDC should be performed for each analyst and instrument used before compliance samples are analyzed. The variability introduced by multiple sample preparation technicians must also be taken into account. The typical IDC for chemical

measurements consists of demonstrating proficiency in four areas: precision, accuracy (bias), method blank background, and method detection limit. For microbiological methods, the specificity, relative trueness, positive and negative deviation and repeatability should be estimated if possible. This should include a replicate demonstration of negative results on appropriate negative controls and positive results and confirmations on appropriate positive controls. When reviewing the documentation, the auditor should verify that all results, including errors, are reported in the correct units. Laboratories should also record any actions taken to correct performance that does not fall within the acceptable range established by the applicable method. The method detection limits (MDLs) must be calculated in accordance with 40 CFR 136, Appendix B. The qualitative confirmation capability should be determined ascertaining the detection limits for alternate techniques. When unacceptable performance occurs on QC samples, compliance samples should be reanalyzed after acceptable performance has been established.

Laboratories should maintain complete records for the IDC which include the bullet items in the Checklist on page H-16, Initial Demonstration of Capability.

2.3.1 Method Precision and Bias

Method precision and bias measurements should be made for chemical analyses each time an analytical method is used and periodically, as specified in Chapter V, for microbiological contaminants. Precision is calculated using repeated measurements. Bias measurements are made by spiking samples or reagent water with known concentrations of analytes or suspensions of microorganisms, and measuring the resulting percent recovery. Laboratories should develop standard operating procedures for this purpose that are consistent with the quality control requirements specified in Chapters IV, V and VI of this Manual, unless otherwise specified in the published method.

For microbiology, the laboratory should analyze duplicate positive samples and take part in proficiency testing or inter laboratory comparisons.

For radiochemistry, precision and accuracy are determined from a laboratory fortified sample matrix (spike) with each batch of samples. Samples should be fortified at 1-10 times the MCL or 5-10 times the background.

Laboratories should maintain complete records of method precision and bias, consistent with the specifications of published methods or, if none are included in the method, consistent with stated laboratory standard operating procedures. Method precision and bias records should include the source, preparation date, and concentration(s) of standards used.

These records should be reviewed by the auditor to verify that the limits of precision and bias achieved are consistent with those established in the published method. If measured precision and bias do not fall within acceptable ranges, efforts should be made to ascertain the reason(s) and depending on the nature of the problem, samples may need to be reanalyzed. The laboratory should also record the reason, identify and implement an appropriate corrective action, and document the results of the corrective action.

2.3.2 Demonstration of Low System Background

For chemistry, most EPA methods require the analysis of a reagent blank with each batch of samples to measure the contamination which may be introduced at the laboratory. In general, the value of the reagent blank should not exceed the MDL. If the blank exceeds the MDL, samples should be reanalyzed after the contamination has been found and the problem corrected.

For microbiology, the laboratory should analyze negative controls to demonstrate that the cultured samples have not been contaminated.

For radiochemistry, blanks are used to determine if activity is added to the sample from the reagents. Typically, the background is the instrument background which is subtracted from all sample counts.

2.3.3 Analytical Method Detection Limit for Chemical and Radiochemical Analyses

The method detection limit (MDL) is the minimum concentration of analyte that can be measured and reported with 99% confidence that the analyte concentration is greater than zero.

Laboratories should determine their own method detection limits for all organic, inorganic and radiochemistry methods using the procedure in 40 CFR 136 Appendix B. Each analytical team using a particular analytical method also should determine it's own detection limits. In addition, if several different instruments are used for the same procedure, then the detection limit should be determined for each instrument. The same extracts may be used to determine the detection limits on several instruments with similar sensitivity, if appropriate.

A procedure for measuring method detection limits is described in 40 CFR Part 136, Appendix B. This procedure involves analyzing seven replicate water samples that have been spiked to, or are known to, contain the analyte at a concentration at or near the estimated detection limit. Laboratories should maintain documentation for the bullet items in the Checklist on page H-17, Method Detection Limits.

Although 40 CFR 136, Appendix B, provides several possible approaches to selecting an estimated detection limit for purposes of designing the study, laboratory auditors should recognize that the most reliable method involves an iterative process of measuring achievability of successively lower concentrations until the actual limit of detection is identified. At a minimum, this approach should be used for purposes of establishing the working MDL when a new method is first used by a laboratory. Successive detection limit determinations to verify the limit in the same matrix or establish the limit in a new matrix may not require measurement of detect ability at numerous concentrations, depending on the experience of the analyst. Any procedure that involves measurement of only one concentration should be reviewed carefully to establish that the analyst was able to document that the concentration measured meets the definition of a method detection limit. The spike concentration should be determined by the signal to noise ratio for each analyte. The same concentration for all analytes will not produce acceptable results. The extractions/analyses should be performed over a period of at least three days to provide a more reasonable MDL.

The required detection limits for Radionuclides are listed in the CFR. Detection limits for Radionuclides are determined on the basis of nuclear counting statistics in addition to sample and instrument parameters. Proper counting errors should be calculated for each method and reported with each sample analyses.

2.4 Instrument Calibration and Calibration Records

For all types of analytical instruments, it is important that the analyst establish the relationship between the measured value and the concentration of the analyte in the sample, daily, using accurate reference materials. The calibration should include at least three concentrations in the linear portion of the curve. Additional standards should be used if the curve is nonlinear. The concentrations should be selected to bracket the range of concentrations expected to be observed in the samples to be analyzed. Some organic methods recommend using five concentrations. Some inorganic methods require a blank and three standard concentrations.

Calibration for some methods is very time-consuming. For these methods, the standard curve should be initially developed and thereafter, at the beginning of each day on which analyses are performed, this curve should be verified by analysis of at least one standard in the expected concentration range of the samples analyzed that day or within the operating range. All checks must be within the control limits specified in the method or the system must be recalibrated.

For radiochemistry, efficiency (counts per minute per disintegration per minute) curves should be used to determine

the efficiency for a given mass or nuclide energy. For alpha and beta counters, the change in efficiency should be plotted versus mass to determine the efficiency at a given mass. For gas flow proportional counters, sample composition, size, alpha/beta energy and distance from the detector influence efficiency. For gamma counters, two curves should be prepared, energy versus channel number and efficiency versus energy. For gamma counters, the primary variable is the distance from the source to the detector. Each type of sample container will have a unique gamma efficiency curve. The shape of the curve is intrinsic to the detector material and will be the same for each geometry subject to differences due to distance. The Efficiency is constant for many orders of magnitude. Standards should be prepared at a level of activity so that greater than 1600 counts above background are acquired during the counting time. Under this condition, the uncertainty will be 5% (2SD) at the 95% confidence level. To verify the curve, one or more of the standards should be counted daily when samples are counted. The RSD should not exceed 3SD or 10% of the expected value. Multi term polynomial curves should be generated from the relationship between efficiency and either mass or energy.

Laboratory records should include the concentrations of standards used, a graph of the calibration curve and if possible a description of statistical procedures used to establish the curve, the source of standard materials, date of preparation and a description of standard preparation steps or reference to the SOP. To simplify these records, laboratories may reference a Standard Operating Procedure which specifies the calibration procedures.

Quality control (QC) samples from an outside source should be used to verify all initial calibrations. Two or three QC standard concentrations chosen to bracket the working range are recommended. For radiochemistry counting, the laboratory should use a check source and a background both at the beginning and end of each batch of samples, especially if the counter is not in constant use. Regardless of the number of samples analyzed, a record of a check standard analyzed at the end of each batch should be maintained. In general, if the results of a check sample analysis at the end of a batch exceed the confidence limits (CL) of the method, a system review and corrective action (such as recalibration) are indicated and the samples should be re-analyzed. Laboratories may develop their own guidelines for determining when re-analysis is necessary (where not specified in the method). Such guidelines should be statistically linked to method performance (e.g., plus or minus one standard deviation). Where these guidelines are applied, the auditor should verify that the basis for the guideline is recorded.

Many analysts believe that multiple standard concentrations need not be used to calibrate instruments that provide direct concentration readings because manufacturers of the instruments specify the use of a single standard concentration for calibration. For such instruments, multiple concentrations that bracket the required working range are strongly recommended. These standards should be treated as samples and a record of the instrument readings should be maintained by the analyst. A general rule of thumb is that the measured concentration should be within 10 percent of the actual concentration.

Most methods specify calibration procedures and the auditor should verify that procedures are being followed by the analysts and are consistent with those specified by the method. Where methods do not specify calibration requirements, instrument manufacturers' recommendations or other guidance may be available.

2.5 *Routine Monitoring of Analytical Method Performance*

Laboratory Quality Assurance Plans should specify a reasonable schedule for routine monitoring of method performance based on requirements specified in the approved EPA methods or based on requirements for other similar measurements where the method does not specify a requirement. Most organic and radiological methods specify requirements for periodic monitoring of method performance.

Methods for microbiological analyses require periodic duplicate analyses as a routine check on method performance. Positive and negative controls should also be analyzed on a regular basis and whenever new media is prepared or commercially prepared media is received.

Method performance documentation should include the bullet items listed in the Checklist (page H-19, Routine Performance Checks). Further discussion of these records has been provided in the previous sections.

2.5.1 Laboratory Fortified Blanks

The laboratory should analyze a laboratory fortified blank (LFB) with each batch of samples analyzed. The concentration of the LFB should be ten times the MDL or estimated detection level or equivalent to a mid range standard. At least some portion of the LFBs should be at the laboratory's reporting level. Precision and recovery for the LFBs must be within the criteria specified in the methods or the corrective action specified in the method must be taken. The LFBs must be processed through the entire analytical procedure (e.g., extraction, derivation and detection).

Control charts or limits, generated from mean percent recovery and standard deviation of the laboratory fortified blanks, should be maintained by the laboratory. Until sufficient data are available from the laboratory, usually a minimum of 20 to 30 test results on a specific analysis, the laboratory should use the control limits specified in the methods. See *Standard Methods for the Examination of Water and Wastewater*, part 1020B, or similar QC reference texts for further information. The laboratory should continue to calculate control limits for each analyte as additional results become available. After each five to ten new recovery measurements, new control limits should be calculated using the most recent 20-30 data points. If any of these control limits are tighter than the method specifications, the laboratory should use the tighter criteria. Otherwise, control limits in the methods are required. Control charts are highly recommended even though some of the older methods for inorganic analytes do not include such requirements.

For microbiology, a pure culture of a known positive reaction should be included with a sample batch periodically and when new media is prepared, to demonstrate that the medium can support growth.

2.5.2 Laboratory Fortified Matrix

The laboratory should also fortify a minimum of 10% (or one per batch, whichever is greater) of the routine samples (except when the method specifies a different percentage, e.g., furnace methods) to determine if there are any matrix effects. The spike concentration should not be substantially less than the background concentration of the sample selected for spiking. If the sample concentration is below the MDL, then the analyst may choose appropriate spike levels (e.g., a percentage of the MCL or operating calibration range). This laboratory fortified matrix must be processed through the entire analytical procedure. Over time, to the extent practical, samples from all routine sample sources should be spiked. If any of these checks are not within the control limits specified, and the method was in control as judged by the LFB, the results of that sample should be labeled suspect due to sample matrix.

2.5.3 Quality Control Samples

At least once each quarter, each laboratory should analyze quality control or reference samples from a source other than that from which their standards are purchased (for each method, analyst, and instrument) as a routine check on performance. If errors exceed limits specified in the methods, corrective action should be taken and documented, and a follow-up quality control standard analyzed as soon as possible to demonstrate the problem has been corrected. The laboratory should maintain records for these routine checks.

2.5.4 Blanks

Most of the EPA-approved analytical methods specify analysis of one or more blank samples with every batch of samples analyzed. Follow the method recommendations and requirements. See the discussion of laboratory reagent blanks in section 2.3.2. Laboratory reagent blanks (method blanks) measure the level of contamination that may be introduced at the laboratory. The results of analyzing blank samples should be recorded by the analyst with all other data and checked by the auditor.

Field blanks should also be analyzed to measure contamination which may be introduced from preservatives, storage or at the sampling site. A field blank may be substituted for the reagent blank. However, if the field blank is contaminated, then a reagent blank must be analyzed to determine the source of the contamination. Trip blanks may also be required to determine if contamination occurred during shipping.

All blanks must be processed through the entire analytical procedure.

Most analytical methods specify an acceptable maximum level for the analyte in a blank sample. Some States require that blank results indicating contamination be submitted with the analytical results.

2.5.5 Other Quality Control Requirements

Some methods require duplicate sample analyses, method of standard additions, column or instrument performance check samples, instrument tuning checks, etc. Whenever additional quality control requirements are specified in the method or method manual, they must be followed.

2.5.6 Performance Evaluation Studies

In order to receive and maintain certification, drinking water laboratories must successfully analyze performance evaluation (PE) samples, in accordance with the requirements in the NPDWR. In addition to these samples, laboratories certified for radiochemical analysis must also participate in other performance evaluation studies each year as prescribed by the program. Laboratories are required to maintain records of their performance in those studies and any corrective actions taken in response to performance problems indicated by the study results. A copy of this documentation should be forwarded to the certification officer. Auditors should review these records to determine that all errors or performance problems are addressed and that proper corrective actions have been taken, where appropriate. Auditors should review the raw PE data to verify that the PE samples were diluted according the instructions provided. The auditor should be able to verify from the raw data (e.g., area counts for GC analysis) that the PE samples were analyzed with the correct dilution factor.

2.6 *Instrument Maintenance*

Proper maintenance of all laboratory instruments and equipment is critical to achieving proper laboratory performance. Instrument manufacturers provide suggested maintenance schedules and laboratories should adhere to such schedules. Laboratories should also record maintenance and repair activities for all instruments.

3.0 Data Handling and Reporting

3.1 *Calculations*

During the data audit, the auditor should review all procedures for calculating final values from the raw data. Laboratories should maintain written standard operating procedures for making all calculations, and all raw data and supporting information needed to recreate the calculations should be available to the auditor. The auditor should verify representative calculations sufficient to provide a reasonable level of confidence that the appropriate procedures are being used consistently. Using the raw data, the auditor should be able to regenerate the sample data reported to the customer.

In cases where the laboratory does not provide documentation for calculation methods and the method used is not readily apparent, the auditor should attempt to verify calculations using techniques normally used by the Regional or State laboratory. If the results do not agree with those reported by the laboratory, the auditor should attempt to ascertain and evaluate the calculation method used. This may require interviewing one or more analysts who routinely make the calculations to determine the step-wise process used and to determine that all analysts in the laboratory are using the same method. To avoid calculation errors, laboratories should implement a policy of requiring that all

calculations be cross-checked by a second analyst. Both analysts should certify the data, by signature with date in ink, and note as acceptable to document that the data has been cross-checked. Where possible, calculations should also be verified by a laboratory supervisor.

3.2 *Use of Significant Figures*

Laboratories should observe conventions concerning proper use of significant figures in making calculations to avoid the appearance that the data are more precise than the method allows. Conventions for the use of significant digits and proper rounding of numbers are discussed in detail in the EPA publication: ***Analytical Quality Control in Water and Wastewater Laboratories*** (EPA-600/4-79-019) and in ***Standard Methods for Examination of Water and Wastewater*** (Section 1050 B in the 18th Edition). As a rule, the significance of an analytical result cannot exceed the significance of the least precise step in the procedure. The numbers resulting from calculations cannot reflect greater precision than the data used to make the calculations. In order to verify that proper conventions have been followed, the auditor should identify the least precise step in the analytical process.
Frequently, the least precise step is the measurement of the sample volume necessary for the analysis, which most often involves the use of a graduated cylinder or pipette. The auditor should verify the actual tolerances of glassware used in the laboratory analytical methods (by examining the glassware) and determine that the appropriate number of significant digits has been carried through all data recording and calculations.

3.3 *Reporting Greater-Than and Less-Than Values*

Less-than values occur frequently in drinking water analysis. For chemical analytes, less-than values should be recorded by the analyst when the measure obtained is below the value of the lowest standard used to generate the calibration curve. These reported less-than values should be followed with the value of the lowest concentration used in the calibration curve (e.g., <0.2). Regulations may require the laboratory to report data, either quantitatively or qualitatively, to the MDL. If this situation exists, laboratories may report data as "detected" less than the lowest standard (e.g., detected <0.2). If the method involves a one point calibration, values may be reported down to the MDL.

Samples with concentrations greater than the highest standard should be diluted to fall within the calibration curve. If unusual circumstances prevent this, results should be reported as greater than the highest standard and another sample should be obtained.

For microbiological contaminants, if the organism of concern is not detected, the analyst may report total and fecal coliform and E. coli as absent and Heterotrophic Plate Count (HPC) as <1 per unit volume. If the concentration is too great, HPC should be reported as too numerous to count.

3.4 *Blank corrections*

Correction of sample data for blank results is an important issue in data reporting. In general, analyte measurements in the blank that exceed allowable levels should be interpreted as an indication of laboratory contamination or other performance problem. Data should never be corrected for blank measurements unless specifically stated in the analytical method being utilized. Laboratories should take steps to isolate and eliminate sources of contamination where blank analyses indicate a consistent and significant problem.

3.5 *Error types*

The auditor should ensure that the laboratory Quality Assurance Plan specifies safeguards for protecting against common types of data errors. In general, procedures for spot-checking data and for verification by a second analyst

are the most common practices used. Some common types of data errors include the following:

- Data entry errors;
- Transcription errors;
- Rounding errors;
- Calculation errors;
- Failure to record or retain data, especially dilution factors;
- Incomplete data reporting (i.e., missing quality control or method performance data);
- Omission of units or incorrect units;
- Improper data error corrections (a single line should be drawn through an incorrect value such that both the correct and incorrect values are legible; change should be initialed and dated);
- Recording data in pencil (data must be recorded in indelible ink to help ensure data integrity);
- Errors in use of significant figures (see section 3.2);
- Errors in logic (for example, applying a blank correction, where allowed by the method, at the wrong step in the calculation);
- For radiochemistry, other errors may occur if the following factors are not considered: yield determinations, decay and/or ingrowth factors, use of proper counting times, and accurate efficiency curves.

Virtually all of these types of errors can be prevented by requiring that all data be checked and initialed and dated by a second analyst (and verified by a laboratory supervisor, if possible) before being recorded for final reporting.

3.6 *General Quality Control Records*

During the data audit, in addition to identifying and reviewing quality control data specific to individual analyses, the auditor should verify that certain general quality control procedures are conducted and that written records or logs are maintained regularly by the laboratory. For example:

- The date on which chemicals arrive in the laboratory and the date that reagents are first opened should be recorded on the bottle label and initialed by the analyst;

- Reference standard calibration solutions should include labels that list the date of preparation, the concentration, and the name of the analyst who prepared the standard;

- Training records for laboratory analysts should include academic background, specialized training courses completed, and chemical analysis and instrument experience;

- Stock standard solution logs should list the preparation date, the concentration, and the name of the analyst who prepared the solution and the dilution solvent;

- GC injection logs should list each sample injected, the time and date of analysis, and the name of the analyst who performed the analysis;

3.7 *Data Security and Back-Up*

Laboratories should maintain data in a secure system to which access is limited. A system for logging files in and out should be maintained so that laboratory files are known to be complete at all times. An original copy of the data report showing all corrections or changes should be maintained on file. Additional copies for use by analysts may also be maintained and tracked. A laboratory manager should certify, in writing (or by using a unique code identifier for electronic reporting), the authenticity of each data report, and maintain such certification records for inspection.

The trend to replace manual operations with computers is expanding rapidly and the data management practices used to protect the integrity of electronic data are becoming increasingly important. Minimum records to be maintained include a description of the hardware and software used; written SOPs that document procedures for generating, validating, and reviewing computer data; and results of periodic in-house QC inspections of electronic data generation and reporting.

Any data stored electronically should be supported with backup files generated in accordance with Agency guidelines specified in the EPA document, ***2185 - Good Laboratory Practices for Automated Data***, 1995 Edition (Office of Information Resources Management, RTP, NC 27711). This guidance document suggests appropriate frequencies for generating backup files and suggestions for off-site storage of copies. One important disadvantage of electronic formats is that they are software and hardware dependent.

DRINKING WATER CERTIFICATION
RECORD KEEPING AUDIT

SAMPLE CHECKLIST			
Field Records	**Yes**	**No**	**Comments**
1.1 Field Sampling			
The following items should be recorded in ink at the time of sample collection as part of the sample tracking record			
• Sample identification number			
• Public Water System ID number (where applicable)			
• Date and time of sample collection			
• Sample type (i.e., compliance, confirmation, etc.)			
• Analyses required			
• Sample container type and size, preservatives, holding time			
• Sample volume or weight collected			
• Name, phone number and organization of sampler			
• Preservatives added to the sample, concentration and amount added			
• Sampling location (site ID number, treatment information, where applicable)			
• Sample shipping procedure and holding time			
• Sample container preparation (i.e., cleaning methods, sterilization technique/date/time/batch number)			
• pH and disinfectant residual from plant measurements if available			
1.2 Field Measurements*			
Field analytical records include the following items:			
• Sample identification number			
• Date and time of each field measurement and time of sample collection			
• Pertinent field data (i.e., temperature, free residual chlorine, and pH)			
• Name of analyst			
• A list of calibration steps and concentrations of standards			
• Date of instrument calibration			
• The type, concentration, preparation date and source of any calibration standards used (e.g., reference buffers for pH and reference materials for disinfectant residual)			

* If performed by laboratory personnel

SAMPLE CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
1.3 Sample Acceptance			
Sample tracking records from field samplers are maintained for all samples			
The following entries are added to the sample tracking form for all samples			
• Name of the person delivering the sample			
• Name of the person receiving the sample			
• Date and time of sample collection and receipt			
• Date and time of sample receipt			
• Condition of samples received (i.e., sealed, unsealed, broken containers, temperature, preservatives noted on label)			
• Sample irregularities are documented at the time of sample receipt (i.e., improper collection, shipping procedure not followed)			
• New sample ID (if assigned by laboratory), which can be cross-referenced to the original sample ID, methods, analysts assigned			
Deficient samples are rejected in accordance with written laboratory policy			
Sample rejection log is maintained			
Maximum holding time not exceeded			
Replacement sample requested for rejected sample			
1.4 Sample Storage			
Samples are properly labeled and securely attached			
Samples exceeding holding times are discarded			
Volatiles are hermetically sealed			
Samples requiring special handling are properly stored (i.e., light sensitive, temperature sensitive, radioactive)			

DRINKING WATER CERTIFICATION
DATA AUDIT

CHEMISTRY LABORATORY ANALYSIS REVIEW CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
2.1 Analytical Methods			
Analytical procedures (SOPs) are listed and referenced in the laboratory's Quality Assurance (QA) Plan for all analytes measured and this listing accurately reflects the analytical methods employed by the laboratory.			
Only EPA-approved methods are used to analyze drinking water compliance samples			
Method procedures are followed exactly by the laboratory personnel or allowed deviations are listed in SOPs			
Written Standard Operating Procedures (SOPs) are consistent with the approved methods and are followed by the laboratory personnel			
2.2 Instrument Performance			
Laboratory monitors and documents instrument performance characteristics regularly, in accordance with the method specifications and the equipment manufacturer's recommendations			
Instrument performance records are maintained and include the following items:			
• Initial demonstration of capability			
• Determination of linear dynamic range			
• Method Detection Limits			
• Initial and routine instrument calibration			
• Performance on standard reference materials and/or QC check samples			
• Instrument sensitivity and stability			
• Tuning checks			
Laboratory equipment such as analytical balances and thermometers are calibrated against standards traceable to NIST			
Equipment stability records such as dry oven, incubator, refrigerator, autoclave, and block digester temperatures are maintained			
2.3 Initial Demonstration of Capability			
Method performance is demonstrated as specified by the published method or if not specified, A minimum of four replicates of a quality control or reference sample are processed through all steps of the analytical procedure*			
Method performance is validated for all analytes measured			
Analytes are measured at levels within the required method performance range			
Initial method precision and bias criteria are met			
The method is validated for each analyst and each instrument the analyst uses			
Variation due to multiple sample preparation technicians is taken into account			
System background is below the MDL			
MDLs are calculated for all analytes			

* If no other requirements are specified by the published method.

CHEMISTRY LABORATORY ANALYSIS REVIEW CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
Qualitative capability is identified for each analyte			
Method validation records are maintained and include the following items:			
• Name and/or number of the analytical method			
• Name of analyst			
• The type of test			
• Date and time of analyses			
• Instrument identification number			
• Number of replicates analyzed			
• Concentrations of the standards used			
• A description of any standard preparation steps (preparation date, name of the analyst who prepared the standard, and the reagents used)			
• Source of the standard material and preparation date			
• All calculations and supporting data			
Calculated error is expressed in the same units as the reported data			
Corrective action is documented and resulting performance is reported where method performance is outside acceptable ranges			
2.3.1 Method Precision and Bias			
Method precision and bias measurements are conducted as specified by the published method or Precision and bias measurements follow the standard operating procedures developed by the laboratory*			
Method precision and bias are determined for all analytes measured			
Method precision and bias are determined at the correct frequency			
Method precision and bias control limits are met for all analytes measured			
Precision records are maintained for each instrument and include the following items:			
• Name and/or number of the method			
• Name of analyst			
• Date and time of analyses			
• The number of replicates analyzed			
• All calculations and supporting data			
A minimum of 10% of routine samples are spiked and analyzed (unless the method specifies a different percentage)			
Spiked sample records are maintained and include the following items:			
• Name and/or number of the method			
• Name of the analyst			
• Date and time of analyses			
• Spike amounts added to samples			

* Where no requirements are specified by the published method

CHEMISTRY LABORATORY ANALYSIS REVIEW CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
• Concentration of the check standard used			
• Source of the standard material			
• A description of any standard preparation steps (preparation date, name of the analyst who prepared the standard, and reagents used)			
• All calculations and supporting data			
Quality Control charts (% recovery vs time) are maintained or QC limits calculated			
Corrective action is documented and re-analysis results are reported where precision and bias limits fall outside acceptable ranges			
2.3.2 Method Detection Limits			
Method detection limits (MDLs) are measured for all analytical methods			
Each analyst measures their own detection limit for each analytical method and instrument used in the procedure			
MDLs are determined by the procedure described in 40 CFR Part 136 Appendix B			
MDL records are maintained and include the following items:			
• Name and/or number of the method			
• Date of sampling and date of analyses			
• Identification of the analyst			
• The MDL achieved and the method's published MDL (in appropriate units)			
• Analyte level spiked or in the sample			
• Number of replicates analyzed			
• A description of any allowable variations used in the method			
• A description of the type of water in which the MDL is measured			
• A description of the procedure used to determine the MDL(iterative process used?) and a description of the process used to estimate the MDL			
• Analyte recovery values of reference materials or spiked samples			
• All raw data and calculations necessary to reconstruct MDL determination			
2.4 Initial Instrument Calibration			
Initial calibration is conducted as specified by the published method or Three or more concentrations should be analyzed. The lowest calibration standard measured should be near the reporting level, and the remaining concentrations bracket analyte levels*			
Instruments are calibrated for all analytes measured			
Standard calibration materials are from a different source than the QC standards			
Analytes are measured at concentrations covering the sample concentration range			
Instruments are calibrated at the correct frequency as specified by the method and/or the instrument manufacturer's recommendations			

* Where no requirements are specified by the published method

CHEMISTRY LABORATORY ANALYSIS REVIEW CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
Calibration records are maintained for each instrument and include the following items:			
• Name and/or number of the analytical method			
• Date and time of calibration measurements			
• Name of the analyst			
• Concentrations of the standards used			
• A description of any standard preparation steps (preparation date, the name of the analyst who prepared the standard, and reagents used)			
• Source of the standard material			
• Labeled graph of the calibration curve			
• A description of any statistical procedures used to establish the curve			
• All calculations and supporting data			
Instrument sensitivity (calibration curve slope) is documented			
Continuing Instrument Calibration			
Calibration check standards are routinely measured as specified by the published method or One or more check standards chosen to bracket analyte concentrations are measured each working day, and a mid-point calibration standard is measured after each batch*			
Instrument response is checked for all analytes measured at the required frequency			
Analytes are measured at concentrations appropriate for the sample concentration range			
Calibration check standards are analyzed at the correct frequency as specified by the method or the Manual for Certification of Laboratories Analyzing Drinking Water			
Calibration curves are verified for all analytes measured			
Routine calibration records are maintained for each instrument and include the following items:			
• Name and/or number of the analytical method			
• Date and time of check standard measurements			
• Name of the analyst			
• Concentration of check standards used			
• Source of standard materials			
• A description of any standard preparation steps			
• All calculations and supporting data			
Calibration procedures are consistent with those specified in the methods and are followed by laboratory analysts			
Corrective action (recalibration) is documented and re-analysis results are recorded where check standard results do not meet method criteria			
Written guidelines for recalibration and re-analysis are available*			

* Where no requirements are specified by the published method

CHEMISTRY LABORATORY ANALYSIS REVIEW CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
2.5 Routine performance checks			
Quality control (QC) or referenced materials are analyzed quarterly or as specified by the published method			
LFBs are analyzed for all analytes measured at the required concentration			
LFBs are analyzed at the correct frequency			
Method bias (% recovery) criteria is met for all analytes measured			
QC or reference check samples are routinely analyzed for each method, analyst, and instrument			
Performance check records are maintained and include the following items:			
• Name and/or number of the analytical method			
• Name of the analyst			
• The type of test			
• Date of analysis			
• Concentration of the standard used			
• A description of any standard preparation steps (preparation date, the name of the analyst who prepared the standard, and reagents used)			
• Source of the standard material			
• Method precision and bias			
• QC sample results			
• PE sample results			
• Matrix spike results			
• All calculations and supporting data			
2.5.1 Laboratory Performance Evaluation			
The laboratory analyzes, at least annually, water supply performance evaluation samples within EPA limits			
Performance evaluation study records are maintained			
Corrective action is documented where performance problems are indicated by the study results			
2.6 Instrument Maintenance			
Instrument maintenance schedules from manufacturers are followed and maintenance activities are documented			
Repair activities are recorded for all instruments			

DRINKING WATER CERTIFICATION
DATA AUDIT

(The data audit information in this checklist is also included in Chapter 5. Microbiology laboratories do not have to refer to this checklist. The Chapter 5 checklist superseeds this checklist which is included only for Appendix completeness.)

MICROBIOLOGY LABORATORY ANALYSIS REVIEW CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
Laboratory Equipment, Supplies, and Materials			
pH Meter			
Commercial buffer solutions are dated when received and discarded before expiration date			
pH meter is standardized each use period with pH 7.0 and eithr 4.0 buffers or 10.0 buffer			
pH buffer solutions not reused to calibrate pH meter			
Balance			
Balance is calibrated monthly using ASTM type 1 or 2 weights. If non-reference weights are used, non-reference weights are calibrated using type 1 or 2 reference weights			
Correction data available with type 1 or 2 weights			
Annual service contract or internal maintenance protocol and records maintained			
Temperature Monitoring Device			
Glass or electronic thermometers are checked annually and dial thermometers checked quarterly at the temperature used against a reference NIST thermometer or one meeting the requirements of NIST Monograph SP 250-23			
Continuous recording devices used to monitor incubator temperature are recalibrated annually against a NIST thermometer or one meeting the requirements of NIST Monograph SP 250-23			
Incubator			
Temperature is recorded twice daily for days in use, with reading separated by a least four hours			
Autoclaves			
Date, contents, sterilization time, and temperature are recorded for each cycle			
Service contract or maintenance protocol is established			
Heat sensitive tape, spore strips or ampules, or maximum temperature registering thermometer are used during each autoclave cycle			
Automatic timing mechanism is checked for accuracy with a stop watch			
Hot air ovens			
Date, sterilization time, and temperature are recorded for each cycle			
Conductivity meter			
Conductivity meter is calibrated monthly with a 0.01 M KCl solution or lower concentration			

MICROBIOLOGY LABORATORY ANALYSIS REVIEW CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
Refrigerator			
Temperature is recorded for days in use			
Membrane filters and pads			
Lot numbers of membrane filters and the date received are recorded			
Sterility is determined of each lot of membrane filters by placing one membrane filter in non-selective broth medium			
Ultraviolet lamp			
Lamp used for sanitization is tested every quarter			
General Laboratory Practices			
Sample containers			
Sterility of each lot of sample bottles or pre sterilized sample bags is determined by adding non-selective broth, incubating at 35°C for 24 hours and checking for growth			
Reagent water			
Reagent water is tested to assure the minimum requirements are met (see the Manual for the Certification of Laboratories Analyzing Drinking Water, Chapter V, section 4.3.2, for parameter values and test frequencies)			
Dilution/rinse water			
pH of stock phosphate buffer solution is 7.2 ±0.2			
pH of peptone water is 6.8 ±0.2			
Dilution water is checked for sterility			
Glassware washing			
Inhibitory residue test is performed on clean glassware			
Analytical media			
Media preparation records include:			
- Date of preparation			
- Type of medium			
- Lot number			
- Sterilization time and temperature			
- Final pH			
- Technician's initials			

MICROBIOLOGY LABORATORY ANALYSIS REVIEW CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
For liquid media prepared commercially, the following are recorded:			
- Date received			
- Type of medium			
- Lot number			
- pH verification			
Each commercial lot of medium and each batch of laboratory prepared medium is checked before use with positive and negative culture controls, and results recorded			
EC medium + MUG (for E. coli)			
Each lot of commercially prepared medium, or batch of laboratory-prepared medium, is checked with positive and negative culture controls, and results recorded			
Nutrient Agar Medium + MUG (for E. coli)			
Quality of medium lot/batch is evaluated by spot-inoculating control bacteria			
Performance evaluation sample is satisfactorily analyzed annually (if available)			
Analytical Methodology			
A coliform test is conducted quarterly on known coliform-positive and fecal- or E. coli-positive sample			
Duplicate analyses are performed on 5% of samples[2]			
Membrane filter technique (for total coliform in drinking water)			
Sterility check is conducted on each funnel in use at the beginning and end of each filtration series. If control indicates contamination, all data is rejected and another sample obtained			
EC Medium + MUG Test (for E. coli)			
At least 5% of both MUG-positive results and turbid MUG-negative results are verified for E. coli by the use of a multi-test system (API 20E or equivalent); standard biochemical tests (e.g., citrate, indole, and urease tests); serotyping after biochemical identification; or the indole test at 44.5°C and growth in citrate			

[2] Standard Methods for the Examination of Water and Wastewater, 18th Ed., 9020

MICROBIOLOGY LABORATORY ANALYSIS REVIEW CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
MF procedure (for total coliform in source water)			
Sterility check is conducted on each funnel in use at the beginning and end of each filtration series. If control indicates contamination, all data is rejected and another sample obtained			
If two or more analysts are available, each counts the total coliform colonies on same membrane at least monthly. Colony counts agree within 10%			
Multiple tube fermentation technique (for total coliform in source water)			
Completed test is performed quarterly on coliform-positive tube(s)/bottles			
Fecal coliform membrane filter procedure (for fecal coliform in source water)			
Sterility check is conducted at beginning and end of each filtration series. If control indicates contamination, data rejected and another sample obtained			
If two or more analysts are available, each counts the total coliform colonies on same membrane at least monthly. Colony counts agree within 10%			
Date and start time are recorded for each analysis			

DRINKING WATER CERTIFICATION
DATA AUDIT

RADIOCHEMISTRY LABORATORY ANALYSIS REVIEW CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
Analytical Methods			
Analytical procedures are listed and referenced in the laboratory's Quality Assurance (QA) plan for all analytes measured and this listing accurately reflects the analytical methods employed by the laboratory.			
Only EPA-approved methods are used to measure radioactivity in drinking water			
Published methods are followed exactly by the laboratory personnel			
Written Standard Operating Procedures (SOPs) are consistent with the approved methods and are followed by the laboratory personnel			
Initial Demonstration of Capability			
Initial Instrument Calibration			
Initial instrument calibration is conducted as specified by the published method or A background sample and one or more standard materials are analyzed at a minimum of 3 different concentrations.			
All radionuclides are calibrated against standards traceable to NIST			
Standards are measured at concentrations covering the sample concentration range			
Instruments are calibrated at the correct frequency as specified by the method and/or the instrument manufacturer's recommendations			
Calibration standards are reported with the analytical results[3]			
The following items are recorded for the standard material used for each radionuclide analyzed[4]:			
A description of the solution (i.e., the principal radionuclide, mass or volume, and chemical composition)			
The reference time and date			
The measurement result (activity of the principal and possible daughter radionuclides/liter of solution)			
The measurement method			

[3] Standard Methods for the Examination of Water and Wastewater, 16th Ed., 1985

[4] Handbook for Analytical Quality Control in Radioanalytical Laboratories, EPA/600/7-77/088, pg. 4-2

RADIOCHEMISTRY LABORATORY ANALYSIS REVIEW CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
A statement of purity (a list of known impurities, their activities, and how they are measured)			
Decay information			
An estimate of errors (from the measurement themselves and those created by the decay assumption)			
Calibration records are maintained for each instrument and include the following items:			
• The name and/or number of the analytical method			
• Name of the analyst			
• Date and time of analyses			
• Source of the standard material			
• A description of any standard preparation steps (preparation date, name of the analyst who prepared the standard, and reagents used)			
• Counting times			
• Concentrations of the standards used			
• A labeled graph of the calibration curve			
• A description of any statistical procedures used to establish the curve			
• All calculations and supporting data			
Continuing Instrument Calibration			
A background sample and counting check sample are measured every 20 samples or daily if less than 20 samples are analyzed each day[5]			
Radionuclides are calibrated against a standard traceable to NIST			
Standards are measured at a concentration in the sample concentration range			
Counting standards are analyzed at the correct frequency as specified by the method or the Manual for the Certification of Laboratories Analyzing Drinking Water			
Calibration curves are verified for all radionuclides measured			
Check standard records are maintained and include the following items:			
• The name and/or number of the analytical method			
• Name of the analyst			
• Date and time of analyses			

[5] Manual for the Certification of Laboratories Analyzing Drinking Water, Chapter VI, section 7.6.2

RADIOCHEMISTRY LABORATORY ANALYSIS REVIEW CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
• Source of the standard material			
• A description of any standard preparation steps (preparation date, name of the analyst who prepared the standard, and reagents used)			
• Concentration of the counting standard used			
• Counting times			
• All calculations and supporting data			
Precision and Bias			
A minimum of 10 % duplicate samples are analyzed[6]			
Method precision control limits are met for all radionuclides measured			
Precision is determined at the correct frequency			
Precision records are maintained and include the following items:			
• Name and/or number of the method			
• Name of the analyst			
• Date and time of analyses			
• The counter instrument used			
• All calculations and supporting data			
Spiked samples are measured regularly[7]			
Standard materials traceable to NIST are used to spike samples			
Method bias is determined for all radionuclides measured			
Method bias control limits are met for all radionuclides measured			
Spiked sample records are maintained and include the following items:			
• Name and/or number of the method			
• Name of the analyst			
• The date and time of analyses			
• The source of the standards used			
• A description of any standard preparations steps			

[6] Manual for the Certification of Laboratories Analyzing Drinking Water, Chapter VI, section 7.6.1

[7] Handbook for Analytical Quality Control in Radioanalytical Laboratories, EPA/600/7-77/088, pg. 4-11

RADIOCHEMISTRY LABORATORY ANALYSIS REVIEW CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
• Spike amounts added to the samples			
• All calculations and supporting data			
Instrument Performance			
Laboratory monitors and documents instrument performance characteristics regularly, in accordance with the method specifications and the equipment manufacturer's recommendations			
Instrument performance records are maintained and include the following items:			
• Initial and routine instrument calibration			
• Analytical results from field and laboratory blanks			
• Precision and bias			
• Results of inter comparison cross check studies and performance evaluation studies			
• Analytical results from background samples			
Detection Limits[8]			
The detector meets the minimum detectable activity requirements cited in 40 CFR 141.25			
Counting times are listed for each method, instrument, and radionuclide measured. (Sample volumes should be documented for the corresponding counting time)			
Laboratory Performance Evaluation			
The laboratory analyzes, at least annually, water supply performance evaluation samples within EPA limits			
Performance evaluation records are maintained			
The laboratory analyzes, at least semi-annually, EPA inter comparison cross check samples within EPA limits[9]			
Inter comparison cross check records are maintained			
Corrective action is documented where performance problems are indicated by the PE study or inter comparison cross check study results			
Instrument Maintenance			
Instrument maintenance schedules from manufacturers are followed and maintenance records on all radiation instruments and analytical balances are maintained in a permanently bound record[10]			
Repair activities are recorded for all instruments			

[8] Standard Methods for the Examination of Water and Wastewater, 16th Ed., 1985

[9] Manual for the Certification of Laboratories Analyzing Drinking Water, Chapter VI, Section 7.2

[10] Manual for the Certification of Laboratories Analyzing Drinking Water, Chapter VI, Section 7.5

DRINKING WATER CERTIFICATION
DATA AUDIT

DATA HANDLING AND REPORTING CHECKLIST			
Laboratory Records	**Yes**	**No**	**Comments**
Calculations			
Written procedures for all calculations are available for review			
Representative calculations are available and indicate that routine calculations are consistent with the written procedures			
All raw data and supporting information needed to recreate calculations are available for review			
All calculations are cross-checked by a second analyst			
All data and calculations are certified by two analysts by signature with date in ink			
QA plan includes SOP for preventing data errors			
Sample and PE calculations verified by the auditor			
Significant Figures			
Significant figure conventions are followed			
The appropriate number of significant figures are carried out through all recorded data and calculations			
The least precise step is identified in the calculations and the number of significant figures is an accurate reflection of the actual tolerances of the instrument or equipment used in this step.			
Greater-Than and Less-Than Values			
Analyte concentrations with greater-than values are quantitatively diluted and reanalyzed when possible			
Less-than values are reported as "less than" (<) followed by the concentration of the lowest standard used in the calibration curve or the MDL			
For microbiological contaminants not detected, fecal coliform and E. Coli are reported as absent and Heterotrophic Plate Count (HPC) as < 1 per unit volume			
For microbiological contaminants, greater than values for HPC are reported as "too numerous to count" (TNTC)			
Blank Corrections			
Blank results are recorded with all other data and meet method specifications			
Blank measurements exceeding allowable analyte levels are reported and the affected data are flagged			
Data are never corrected for blank measurements unless specifically stated in the analytical method utilized			
Corrective action is documented to isolate and eliminate sources of contamination where blank analyses indicate a consistent and significant problem			

DATA HANDLING AND REPORTING CHECKLIST

Laboratory Records	Yes	No	Comments
Data Security and Back-Up			
A secure data system is maintained with limited access			
Procedures are in place to prevent unauthorized access			
Procedures are in place to protect the integrity of the data			
A log is maintained for laboratory file entries and retrievals			
Computer software is documented and adequate for use			
Original copies of analytical data and calculations (showing all corrections or changes) are maintained on file and copies are tracked			
Electronically stored data are supported with back up files			